MALARIA AND TB: IMPLEMENTING PROVEN TREATMENT AND ERADICATION METHODS

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OF THE

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MALARIA AND TB: IMPLEMENTING PROVEN TREATMENT AND ERADICATION METHODS

TUESDAY, APRIL 26, 2005

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS
AND INTERNATIONAL OPERATIONS,
COMMITTEE ON INTERNATIONAL RELATIONS,
Washington, DC.

The Subcommittee met, pursuant to call, at 2:05 p.m. in room 2172, Rayburn House Office Building, Hon. Christopher H. Smith, (Chairman of the Subcommittee) presiding.

Mr. SMITH. Good afternoon everybody. I am pleased to convene this hearing of the Subcommittee on Africa, Global Human Rights and International Operations today.

We will be examining the U.S. Government's effort to combat two killer diseases, malaria and tuberculosis, which are ravaging the developing world.

The bad news is sobering. One-third of the world is infected with TB bacterium, and it is the leading cause of death for people with HIV/AIDS.

There is a TB explosion in Africa today due to the AIDS pandemic, and sub-Saharan Africa is staggering under the burden of the highest TB rates in the world. Tuberculosis accelerates the progression of HIV, making people sicker sooner.

Similarly, malaria is the number one killer of children and pregnant women in Africa and one of the top killers in Asia and South America. An estimated 600 million people contract malaria each year, resulting in between one and two million deaths. Almost 3,000 children die from the disease each and every day.

Infection rates for malaria dwarf that of HIV/AIDS and the vast majority of malaria patients are poor, pregnant women and children under 5 years of age, who die within days.

Believe me, malaria is a dreadful disease. I saw my own father, a combat veteran who contracted the disease in New Guinea during World War II, struggle in the first few years under its effects.

The good news, however, is that both diseases are preventable and curable. DOTS, which stands for Directly Observed Treatment Short-Course, is a WHO-recommended strategy for the detection and cure of standard TB.

Its key elements include a political commitment to detect, treat and monitor infected individuals, which includes a standardized treatment regimen of six to 8 months.

A 6-month course of anti-TB drugs costs only $12 and can produce cure rates of up to 95 percent, even in the poorest coun-

tries. But despite its low cost and proven success, DOTS is reaching only slightly over one-third of people sick with infectious TB.

Malaria, likewise, is inexpensive, easy to treat, and can be controlled with proven successful methods such as combining use of small environmentally safe amounts of insecticide in homes and buildings, distributing insecticide-treated bed nets, treating with drug regimens and focusing on vulnerable populations, such as pregnant women.

Malaria has largely been eradicated in the developed world. A few other countries, which have employed this comprehensive eradication and treatment strategy, have experienced quick, dramatic reductions in infection rates.

In Zambia's copperbelt, for example, a privately-funded malaria control program, begun in 2000, which included insecticides spraying, saw a decline in malaria cases of 50 percent in just one season.

Today malaria cases are down 80 percent and the number of deaths are down even further with the introduction of newer and better drugs.

Malaria has largely been eradicated in northern regions of South Africa, thanks to a similar campaign funded by the South African private donors and by the Global Fund.

The purpose of this hearing today is to examine our own foreign assistance efforts to eradicate these two scourges and mitigate the suffering and deaths of millions of women and children. Frankly, I am concerned.

In the last 7 years since the U.N. Roll Back Malaria Partnership first set its goals to halve malaria rates, rates have instead increased steadily by 10 percent. As the rates of HIV/AIDS have grown, TB rates are skyrocketing.

The U.S. response to HIV/AIDS is heartening, but not enough attention is being paid, in my opinion, to addressing TB and malaria.

The President's Emergency Plan for AIDS Relief, approved by the 108th Congress, included authorization for the U.S. Government to treat those infected with malaria and TB.

However, other than those who are infected with HIV, it is my understanding that none of these funds have been spent for treatment of a single person infected with malaria or tuberculosis.

USAID's Child Survival and Health programs spend approximately $80 million, respectively, for malaria and TB programs annually. For fiscal year 2006, the Administration is requesting $139 million, a decrease of $30 million from the previous year's level, primarily to strengthen TB and malaria prevention and control programs at the country level.

Budget request documents state that malaria treatment programs will focus on expanding access to insecticide-treated bed nets, intermittent treatment for pregnant women and the rollout of a new combination of drug therapies. TB programs, which expand and strengthen DOTS' strategy at the country level are the focus of USAID's TB program.

My response to these proposed programs is that it appears we are doing more of the same, but at reduced funding levels. But, more of the same is not necessarily going to roll back malaria or stop the escalating rates of TB.

In our HIV/AIDS strategy, we spend approximately one-third of the funds for treatment programs. Why are spending levels only 7 percent of our malaria program funds on direct interventions, when so many lives could be saved by getting the right drugs and the right tools to the most vulnerable?

I look forward to the testimonies of our expert witnesses, both from the government and from the private sector.

I hope to hear good news on how we are strategically targeting areas where we have and can have a great impact, how we are documenting that our dollars are producing real results, and how we are indeed saving lives.

I would like to yield to my friend and colleague, Mr. Payne, for any opening comments he might have.

[The prepared statement of Mr. Smith follows:]

PREPARED STATEMENT OF THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS AND INTERNATIONAL OPERATIONS

The Subcommittee will come to order. I am pleased to convene this hearing of the Subcommittee on Africa, Global Human Rights and International Operations. Today we will be examining the U.S. government's efforts to combat two killer diseases, Malaria and Tuberculosis, which are ravaging the developing world.

The bad news is sobering. One-third of the world is infected with the TB bacterium, and it is the leading cause of death for people with HIV/AIDS. There is a TB explosion in Africa today due to the AIDS pandemic, and sub-Saharan Africa is staggering under the burden of the highest TB rates in the world. Tuberculosis accelerates the progression of HIV, making people sicker sooner.

Similarly, Malaria is the number one killer of children and pregnant women in Africa, and one of the top killers in Asia and South America. An estimated 600 million people contract malaria each year, resulting in between one and two million deaths, and almost 3,000 children die from the disease *every day*. Infection rates for malaria dwarf that of HIV/AIDS, and the vast majority of malaria patients are poor pregnant women and children under five years old, who die within days.

Believe me, malaria is a dreadful disease. I saw my own father, a combat veteran who contracted the disease in New Guinea during World War II, struggle under its effects for years.

The good news, however, is that both diseases are *preventable* and *curable*. "DOTS," which stands for "Directly Observed Treatment, Short-Course," is the WHO-recommended strategy for the detection and cure of standard TB. Its key elements include political commitment to detect, treat, and monitor infected individuals, which includes a standardized treatment regimen of six to eight months. A six-month course of anti-TB drugs costs only $12 and can produce cure rates of up to 95% even in the poorest countries. But despite its low cost and proven success, DOTS is reaching only slightly over one-third of people sick with infectious TB.

Malaria, likewise, is inexpensive and easy to treat, and can be controlled with proven successful methods combining use of small, environmentally safe amounts of insecticide in homes and buildings; distribution of insecticide-treated bed nets; treatment with drug regimens; and focus on vulnerable populations, such as pregnant women.

Malaria has largely been eradicated in the developed world, and a few countries which have employed this comprehensive eradication and treatment strategy have experienced quick, dramatic reductions in infection rates. In Zambia's copperbelt, for instance, a privately-funded malaria control program begun in 2000, which included insecticide spraying, saw a decline of malaria cases of 50% in just one season. Today malaria cases are down 80%, and the number of deaths down even further with the introduction of newer and better drugs. Malaria has been largely eradicated in northern regions of South Africa, thanks to a similar campaign funded by South African private donors and the Global Fund.

The purpose of this hearing today is to examine our own foreign assistance efforts to eradicate these two scourges and mitigate the suffering and deaths of millions of women and children. And frankly, I am concerned. In the seven years since the UN Roll Back Malaria Partnership first set its goal to halve malaria rates, rates have instead increased steadily by ten percent. As the rates of HIV/AIDS have

grown, TB rates are skyrocketing. The U.S. and global response to HIV/AIDS is heartening, but not enough attention is being paid to addressing TB and Malaria.

The President's Emergency Plan for AIDS Relief approved by the 108th Congress included authorization for the U.S. government to treat those infected with malaria and TB. However, other than those also infected with HIV, none of these funds has been spent for treatment of a single person infected with malaria or tuberculosis.

USAID's Child Survival and Health programs spend approximately $80 million respectively for malaria and TB programs annually. For FY 06, the Administration is requesting $139 million, a *decrease* of $30 million over the previous year's level, primarily to strengthen TB and malaria prevention and control programs at the country level. Budget request documents state that malaria treatment programs will focus on expanding access to insecticide treated bed nets, intermittent treatment for pregnant women, and the roll-out of new combination drug therapies. TB programs which expand and strengthen the DOTS strategy at the country-level are the focus of USAID's tuberculosis program.

My response to these proposed programs is that it appears we are doing more of the same—at even reduced funding levels. But more of the same is not going to roll back malaria, or stop the escalating rates of TB. In our HIV/AIDS strategy, we spend approximately one-third of funds for treatment programs. Why are we spending only seven percent of our malaria program funds on direct interventions, when so many lives could be saved by getting the right drugs and the right tools to the most vulnerable?

I look forward to the testimonies of our expert witnesses both from the government and from the private sector. I hope to hear good news stories of how we are strategically targeting areas where we can have an impact; how we are documenting that our dollars are producing real results; and how we are saving lives.

Mr. PAYNE. Thank you very much. Thank you, Mr. Chairman. Let me take this opportunity to thank you for calling this very important hearing on malaria and TB, implementing proven treatment and eradication methods.

This is important because we have to see what has been done and what more should be done to address the scourge of malaria and TB in the developing world in general, but in Africa in particular.

There is a health emergency in Africa and parts of Asia—India in particular—and we have a responsibility as the United States to attempt to do more about this serious problem.

I think our contributions to the Global Fund to fight HIV/AIDS, tuberculosis, and malaria, though they have increased over the years, should be increased even more. It is such a dreaded disease and is having such a tremendous impact on the world's population that I think that we can do more.

In terms of the U.S. contributions, approximately $1.52 billion has been made available to the Global Fund through fiscal year 2005.

When Global Fund advocates say that we should be contributing more, the Administration's response is that the United States would be able to pay more if other countries met their pledges, because our legislation requires that the U.S. contributions for fiscal years 2004 through 2008 not exceed 33 percent of the contribution from all other sources.

I think this is a situation where the U.S. should exert its influence over our friends and allies to urge them to step up to the plate in their contributions, but also I think that perhaps we therefore ought to take a look at the legislation that we passed preventing us from spending more than one-third.

Perhaps in this instance we should make an allowance, because we don't always have a one-third level in things that we do in other areas.

That is a question, should one-third be sacrosanct? Should it be placed in concrete? Should it be immoveable, especially since it is preventing us from actually saving lives?

But I think that this is a situation where we should continue to try to urge others to do more. As I said, we have provided a good deal to the Global Fund, but to put things in perspective, for example, the EU has given more than the U.S. in actual dollars, as well as percentage-wise.

In fiscal year 2003 and fiscal year 2004, the President's request was only for $200 million to the Global Fund and Congress keeps increasing that amount in appropriations, but it raises questions about whether the Administration has this as a top priority.

In 2004, at the International AIDS Conference in Thailand, U.N. Secretary-General Kofi Annan urged the U.S. and EU to each contribute $1 billion to the Global Fund and that $1 billion could come from other sources.

The response from the U.S. global AIDS coordinator, Randall Tobias, regarding whether the U.S. would be contributing that amount was that it is not going to happen. Later he went on to say that the United States is urging the Global Fund to slow down and that because of amounts already in the pipeline, they have adequate resources on hand.

These comments by our global AIDS coordinator are both disturbing and, in my opinion, irresponsible. This is the exact opposite message we want to send to other countries as we are attempting to get them to increase the ante. It is counterproductive and absolutely makes no sense.

We should be encouraging others to step up their contributions. This is the kind of leadership that is needed on this issue.

While Ambassador Tobias is saying that the Global Fund has enough money, we are actually decreasing our funding of infectious diseases in Africa, the region in need of the greatest attention on HIV/AIDS, tuberculosis and malaria, as well as other public health issues, such as polio, which as we know, 3 years ago was restricted to only six countries in the world with 1,800 cases. That number has tripled and has exploded in the past year or 2, and that is a trend in the wrong direction. We thought that polio was about to be totally eradicated, but it is going in the wrong direction.

The Kawanas clubs are really still doing an outstanding job worldwide, but we need to do more on our level. The President's request for infectious diseases in Africa, which includes tuberculosis, malaria, polio and others, is cut for fiscal year 2006 to $49.5 million, from $72.7 million in 2005.

Overall, global TB and malaria funding is down to $109 million in fiscal 2006, from $168.6 million in fiscal year 2005. Even if you take the amount in the Global Fund for tuberculosis and malaria and add it to our bilateral programs, our 2006 funding is still down.

Meanwhile tuberculosis is on the rise in Africa. Malaria is still the number one killer in Africa and people with HIV and AIDS are dying mostly from tuberculosis and malaria.

We also must take into account the serious issue of co-infection of HIV and tuberculosis. The number of TB cases has risen dramatically because of HIV and AIDS. As we know, there is a connec-

tion between the immune system and the susceptibility of tuberculosis to really flourish when the immune system is attacked.

So we have to get serious about funding these programs. We must not undercut core program development assistance programs, while we increase our funding for global HIV and AIDS through PEPFAR or the Global Fund.

I look forward to hearing from our witnesses and appreciate once again the Chairman calling this very important hearing. Thank you.

Mr. SMITH. Thank you very much, Mr. Payne.

The good news is that the witnesses' microphones work. The good news for some is that ours don't, but I would like to yield to Ms. McCollum for any opening statement.

Ms. MCCOLLUM. I have got two of them on now. Thank you, Mr. Chairman. I am anxious to hear the testimony.

I had the privilege of being at a press conference earlier today to draw attention to the plight of many in this world who suffer from malaria and I am just going to take a few minutes to read an excerpt from that.

The human misery and economic destruction caused by malaria in Africa is real and it must be changed. We have the tools to slow down malaria's destructions: Bed nets, improved sanitation, improved drug treatment, appropriate pesticide use and a committed global partnership to provide resources and help strengthen national health systems to fight malaria, as well as tuberculosis and HIV infection.

Every year across the African continent, more than 1 million babies, toddlers, and children under 5 years old die from malaria. This is an unimaginable number of children dying last year.

If you think of the children who died last year in Africa and then just compare it to my State, Minnesota, every single child under the age of 15 years would have died in Minnesota. One million African children are dying in a single year from a preventable disease and this is beyond my comprehension, but the fact is reality and the reality is that this can and must be changed.

For those of us who are moms and dads, we know that small children burning with fever don't scream. They just whimper silently and stare into your eyes and look up. Their voices are not heard.

More than 1 million African moms stare back into the eyes of their children and, tragically, they watch them die from a disease that can be prevented, treated, and defeated.

If the world comes together with the resources and the determination and the urgency to defeat malaria, we will have done our job here.

I want to thank the Chair for having this very important hearing and today we will begin to hear those 1 million tiny voices. Today we will begin to look back into their eyes and show our compassion and our commitment. Thank you, Mr. Chair.

Mr. SMITH. Thank you.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman, and thank you, Ranking Member Payne, for holding this important hearing today and for

allowing me, not a Member of the Subcommittee but the Full Committee, to participate.

TB and malaria, as we know, take over 3 million lives every year, and combined with the growing threat of HIV/AIDS, these diseases, again as we know, represent the greatest threat to global public health.

While the headlines largely focus on new health threats, these two killers continue to ravage so much of the developing world. The sheer scale of infection often makes TB and malaria seem like an insurmountable challenge, but today there is more opportunity and more hope in fighting these diseases than there has ever been.

TB is the leading cause of infection-related diseases around the world. It is the greatest killer of people of HIV/AIDS worldwide, accounting for, it is believed, about 40 percent of the deaths; of AIDS deaths in Asia and Africa.

In fact, TB has quadrupled in many parts of Africa in the last decade, due to the HIV co-epidemic. Despite these formidable statistics, TB remains entirely preventable and curable and treatment is remarkably easy and cheap.

A full course of treatment for TB costs roughly $10 in the developing world. Still proper treatment reaches fewer than one in five infected individuals.

Multi-drug resistant, MDR–TB, is a growing threat posed by global tuberculosis. It is entirely manmade. It is far more expensive to treat than standard TB and it comes, as we know, from incorrect or interrupted treatment and inadequate and unavailable drug supplies.

Alongside our global partner, the U.S. has taken important steps in authorizing and funding expanded treatment for TB, using, as the Chairman said, the DOTS strategy.

A massive scale-up, for example, of DOTS in India has resulted in the treatment of 100,000 cases every month and significantly falling TB rates. Since the implementation of this new program, treatment success rates have more than tripled.

Despite advances around the world, TB is still diagnosed and treated using many of the same tools in place 50 and 100 years ago. A number of organizations, public and private, are working to develop new drugs, new vaccines, new diagnostics so we can reach more TB patients and stop this global killer from spreading.

A U.S. investment in these efforts is critical to their success. TB treatment programs are often the most important entry point for HIV-infected people.

As the President's Emergency Plan for AIDS relief enters its third year, we have a real opportunity to better coordinate our work with our partners in the 15 targeted countries to help to best fight both of these diseases.

It is vital that all AIDS patients under PEPFAR are also treated for TB, as we could keep hundreds of thousands of people alive, perhaps for years longer.

I thank the witnesses for joining us. I especially thank Chairman Smith and Ranking Member Payne for a productive hearing.

Mr. SMITH. Let me now welcome our two distinguished witnesses, beginning with Dr. Mark Dybul, who is currently Assistant

U.S. Global AIDS Coordinator and Chief Medical Officer of the Office of the U.S. Global AIDS Coordinator in the State Department.

Dr. Dybul is on detail from the Department of Health and Human Services, where he is the Assistant Director for Medical Affairs at the National Institute of Allergy and Infectious Diseases, the National Institutes of Health and Co-Executive Secretary of the HHS–HIV Therapy Guidelines for Adults and Adolescents.

Prior to beginning his role in the Coordinator's Office, he served on the planning task force for President Bush's Emergency Plan for AIDS Relief. He was the lead on President Bush's initiative to prevent mother-to-child transmission of HIV in Africa and the Caribbean. In addition, Dr. Dybul is a former member of the World Health Organization's writing committee to develop global HIV therapy guidelines.

We will then hear from Mr. Michael Miller, who is the Deputy Assistant Administrator of the Bureau for Global Health at USAID, a position he begin in March, 2004. His duties include policy direction and oversight of the Office of HIV/AIDS, the Office of Health, Infectious Disease and Nutrition.

In 2001 and 2002, Mr. Miller was the Director for African Affairs on the National Security Council staff at the White House, with specific responsibilities for East Africa, the Horn of Africa, and for HIV issues globally.

Additionally, he served as advisor to the President's special envoy for peace in Sudan. He participated in diplomatic missions to the region and in the initiation of the peace negotiations.

From 1995 to 2001, Mr. Miller was Legislative Assistant to Senator Bill Frist, where he served on his staff for the Senate Foreign Relations Committee. From 1998 to 2001, Mr. Miller was Staff Director of the Subcommittee in African Affairs, which Senator Frist chaired.

Dr. Dybul, if you could begin.

STATEMENT OF MARK DYBUL, M.D., ASSISTANT U.S. GLOBAL AIDS COORDINATOR AND CHIEF MEDICAL OFFICER, OFFICE OF THE U.S. GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE

Dr. DYBUL. Mr. Chairman, Mr. Payne and Members of the Subcommittee, thank you for this opportunity to discuss President Bush's Emergency Plan for AIDS Relief and its relationship to tuberculosis and malaria in the developing world.

The President and Congress made a strategic decision to focus the Emergency Plan on global HIV/AIDS and particularly on interventions for its prevention, treatment, and care.

Of course, HIV/AIDS in the developing world is closely related to numerous other issues, such as economic development, food security, conflict, the status of women and many more, one of the key linkages is to other infectious diseases.

In much of the developing world, including many of our 15 focus countries of the Emergency Plan, malaria and tuberculosis are also key health challenges, as has been noted by Members of the Committee.

The first point I would like to emphasize is that while the Emergency Plan focuses on HIV/AIDS, its effects will yield benefits in the affected nations across a range of health issues.

This is largely because the U.S., working in support of the strategies of our host nations, is now making major investments in the building of health care capacity. As Ambassador Tobias recently reported to you, those investments have already begun to yield impressive results.

The infrastructure in these nations is perhaps our greatest challenge. We are aggressively promoting the expansion of existing health care networks and the development of new public and private network systems. These network systems have the potential to greatly improve the delivery of health services generally, even in remote areas.

Human capacity is, of course, a prerequisite to the effective functioning of these networks. This Committee is well aware of the desperate shortage of trained health care workers at all levels and the Emergency Plan is supporting training and other mechanisms to overcome the broad impediments to human resource and capacity.

While some of these activities are specific to HIV/AIDS, many of them will lead to improved care across the whole spectrum of health care.

Other components of local capacity on which we have focused include surveillance, reporting, evaluations, strategic information—all tools for accountability.

In all we do, the Emergency Plan also seeks to foster indigenous leadership in the fight against HIV/AIDS. Both accountability and local leadership are, we believe, essential to the development of effective national responses to all health issues.

Now I would like to turn briefly to some specific HIV/AIDS activities we support that also have an affect on other infectious diseases.

Mr. Chairman, as you noted in your opening comments, HIV/AIDS is fueling a resurgence of tuberculosis in resource limited settings. In many areas of our focus nations, it is not uncommon for a majority of HIV-positive people to be co-infected with tuberculosis; tuberculosis is the leading cause of death among those with HIV.

We agree wholly with the suggestions made by Mr. Brown regarding strategies for HIV–TB. As a result, the Emergency Plan supports TB care and treatment for co-infected people.

This includes diagnosis of latent TB infections, treatment to prevent the development of active disease and general TB related care. It is the goal of the Emergency Plan to provide TB therapy, care and treatment for all HIV-infected individuals in the focus countries.

During the initial 8 months of the Emergency Plan, through September 30, the U.S. supported care and treatment for over 240,000 co-infected people in the focus nations. Now, almost 7 months later, the number is certainly much higher.

Because of the high rate of co-morbidity between TB and HIV/AIDS and the high co-infection rate, we are also urging the counseling and testing facilities the U.S. supports to offer HIV testing to those who are present with TB, or other infectious diseases.

Furthermore, it is the formal guidance of the Emergency Plan to encourage HIV testing for all tuberculosis patients in the focus countries.

The Emergency Plan has also developed a basic preventive care package that includes key support and preventive therapies. These packages include products to prevent malaria infection, both for HIV-infected persons and their families, as well as the tuberculosis treatment therapies I have previously mentioned.

Mr. Chairman, the Emergency Plan is experiencing success in support of HIV strategies of our host nations. These accomplishments are also providing valuable assistance as the nations confront the other infectious diseases with which they are burdened.

We, at the Office of the Global AIDS Coordinator, will continue to work with our colleagues at the agencies that have programs focusing on TB and malaria, such as USAID and the Department of Health and Human Services, coordinating those programs with the Emergency Plan efforts, focusing on HIV/AIDS.

I would be happy to address your questions.

[The prepared statement of Dr. Dybul follows:]

PREPARED STATEMENT OF MARK DYBUL, M.D., ASSISTANT U.S. GLOBAL AIDS COORDINATOR AND CHIEF MEDICAL OFFICER, OFFICE OF THE U.S. GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE

Mr. Chairman, Mr. Payne, and Members of the Subcommittee:

Thank you for this opportunity to discuss President Bush's Emergency Plan for AIDS Relief and its relationship to tuberculosis and malaria in the developing world.

The President and the Congress made a strategic decision to focus the Emergency Plan on global HIV/AIDS, and particularly on interventions for its prevention, care, and treatment. Of course, HIV/AIDS in the developing world is closely related to numerous other issues: economic development, food security, conflict, the status of women, and many more.

One of the key linkages is to other infectious diseases. In much of the developing world, including many of our 15 Emergency Plan focus nations, malaria and tuberculosis are also key health challenges.

The first point I would like to emphasize is that while the Emergency Plan focuses on HIV/AIDS, its effects will yield benefits in the affected nations across a range of health issues. This is largely because the U.S., working in support of the strategies of our host nations, is now making major investments in building health care capacity. As Ambassador Tobias recently reported to you, those investments have already begun to yield impressive results.

Infrastructure in these nations is perhaps the greatest challenge. We are aggressively promoting the expansion of existing health care networks and the development of new public and private network systems. These network systems have the potential to greatly improve the delivery of health services generally, even in remote areas.

Human capacity is, of course, a prerequisite to the effective functioning of these networks. This Committee is well aware of the desperate shortage of trained health workers at all levels, and the Emergency Plan is supporting training that covers a broad range of services. While some of this training is specific to HIV/AIDS, much of it will lead to improved care across the whole spectrum of health care.

Other components of local capacity on which we have focused include disease surveillance, reporting, evaluation, and strategic information—tools for accountability. In all we do, the Emergency Plan also seeks to foster indigenous leadership in the fight against the HIV/AIDS pandemic. Both accountability and local leadership are, we believe, essential to the development of effective national responses to all health issues.

Now I'd like to turn briefly to some specific HIV/AIDS activities we support that also have an effect on other infectious diseases.

HIV/AIDS is fueling a resurgence of tuberculosis in resource-limited settings. In many areas in our focus nations, a majority of HIV-positive people are co-infected with TB—a leading cause of death among those with HIV.

As a result, the Emergency Plan supports TB care and treatment for co-infected people. This includes diagnosis of latent TB infection, treatment to prevent development of active disease, and general TB-related care.

During the initial eight months of the Emergency Plan through September 30, the U.S. supported care and treatment for over 240,000 co-infected people in the focus countries. Now, almost 7 months later, the number is certainly far higher.

Because of the high rate of co-morbidity between TB and HIV/AIDS, we are also urging the counseling and testing facilities the U.S. supports to offer HIV testing to those who present with TB or other infectious diseases.

The Emergency Plan has also developed a "basic preventive care package" that includes key support and preventive therapies. These packages include products to prevent malaria infection, as well as the tuberculosis treatment therapies I have previously mentioned.

Mr. Chairman, the Emergency Plan is experiencing success in supporting the HIV/AIDS strategies of our host nations. These accomplishments are also providing valuable assistance as the nations confront the other infectious diseases with which they are burdened.

We at the Office of the Global AIDS Coordinator will continue to work with our colleagues at the agencies that have programs focusing on TB and malaria, such as USAID and the Department of Health and Human Services, coordinating those programs with our Emergency Plan efforts focusing on HIV/AIDS.

I would be happy to address your questions.

Mr. SMITH. Thank you very much, Doctor.

Mr. Miller.

STATEMENT OF MR. MICHAEL MILLER, DEPUTY ASSISTANT ADMINISTRATOR, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

Mr. MILLER. Thank you very much, Mr. Chairman, Mr. Payne, other Members of the Subcommittee. It is certainly my pleasure to be here and testify before you on malaria and tuberculosis.

I am going to hit on a few of the points that Members of the Subcommittee covered. I will also try to frame a discussion from a policy perspective.

Malaria is the number one killer of children in Africa, causing the death of at least 1 million infants and children under 5 every year.

As Ms. McCollum noted, it is hard to get your head around statistics like that. These are children who will never know their own families, who will never have children of their own and have no future.

Tuberculosis or TB, on the other hand, strikes people in their productive years. Worldwide deaths from TB have gone down, except in Africa. Since 1990, they have actually increased. In fact, dramatically.

Two aspects of the disease are especially problematic for policymakers. First, a simple medical fact: Death from these diseases is largely preventable and if addressed in time, can be cured with basic interventions.

Second, while TB deaths are declining worldwide and malaria is effectively eliminated in much of the world, with notable exceptions, both diseases persist in Africa. In fact, the two diseases have grown more deadly in Africa, both in absolute terms and relative to much of the rest of the world. Africa is carrying a greater disease burden than it did two decades ago. Only in the past few years have we seen any clear indication that we might be turning the corner and making progress in some areas.

Why is the problem in Africa so acute and so persistent, when we have seen progress in other parts of the world?

The history of how we got here is vitally important to understand this. The effort to field a comprehensive strategy to combat malaria across Africa is literally decades behind other regions. In the 1950s and 1960s, eradication of malaria was the number one global public health goal. The combination of insecticides and treatments was deployed on a massive scale across entire regions.

In 1955, the World Health Organization's technical panel of the world's top malaria experts met in Kampala, Uganda. There they decided to explicitly exclude tropical Africa from the global malaria eradication program.

The reasons were that the intense and efficient transmission of the disease coupled with a lack of infrastructure made it difficult to undertake such an intensive spraying effort. In short, Africa was left out because it was judged to be too difficult.

Geography and history have conspired against tropical Africa and although we now have the tools and the political will that was not available in 1955, malaria's death grip will not be loosened easily.

Until relatively recently, the backbone of the anti-malaria effort in Africa was limited to the treatment of the disease, once the symptoms appeared. Those drugs are virtually household names, quinine and chloroquine. That one dimensional and unstrategic approach sowed seeds of its own demise. Africa and Africans are still paying the price.

By the 1980s and into the 1990s, malaria death rates were rising at alarming rates in Africa. The reason for the devastation is best characterized as treatment failure. Simply, as the disease adapted and evolved, the drugs stopped offering the protection they once afforded. Populations in malaria areas had no appreciable defense.

Something had to be done. By the early 1990s, the efforts to design and launch a comprehensive strategy for battling malaria in the one place on earth most affected finally began in earnest.

Because of the difficult environment and because of the development of tools unavailable before, the recent response to malaria in Africa does not look like the responses in Central America or Southeast Asia in past decades.

Beginning in about 2000, three new highly efficacious tools became available through USAID and other donors. Combined and fielded together, these measures represent the first truly comprehensive and globally supported anti-malaria strategy to be deployed in the one place that needs it the most.

The first new tool is insecticide-treated nets, or ITNs, as a vehicle to get insecticides into the people's homes. It is very important to note, and we can talk about it later, that getting insecticide into the homes, rather than just talking about spraying versus nets, is really the point.

The second tool is intermittent preventive therapy for women while they are pregnant. This is especially important, because the vulnerability of the child begins before birth.

The third tool is artemisinin-based combination therapies or ACTs. These are new combination drugs, derived from a very old natural Chinese medicine.

ACTs' effectiveness provides a remarkable opportunity to plug the hole left by treatment failure of older therapies and USAID is vigorously supporting their development and availability.

Of course this hearing is not just about malaria in Africa, but also about the scourge of TB, which infects another 1 million Africans every year.

The picture may be less complex by comparison than malaria, but the disease is no less insidious. Close to 2 million people die of TB worldwide every year and of these 2 million, over 30 percent are in Africa.

As mentioned before, one-third of the people walking the surface of the planet are infected with the TB bacilli. As I said before, unlike malaria, TB strikes the most productive and strongest section of the population.

Unlike malaria, the way TB is controlled and treated most effectively is less a point of debate and less likely to vary due to geographic considerations.

What are the prospects of beating TB in Africa? Not as good as we had hoped. Again, while globally we are witnessing an improving picture on TB, Africa still suffered an increasing number of deaths from TB in the past years, more than doubling from about 200,000 in 1990 to 539,000 in 2003.

The factor behind this tragic anomaly is of course HIV/AIDS and the devastating effects of the deadly dynamic of co-infection.

Given the human toll of these two diseases, both of which are curable and in some respects preventable, they are clearly two of the most pressing Africa policy questions we face.

We at USAID are grateful for the opportunity to testify here and we are grateful to the Members of the Subcommittee for their strong support of our efforts to combat these killers. Thank you.

[The prepared statement of Mr. Miller follows:]

PREPARED STATEMENT OF MR. MICHAEL MILLER, DEPUTY ASSISTANT ADMINISTRATOR, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

TUBERCULOSIS AND MALARIA

I would like to thank you for convening this important hearing and for inviting me to testify. Thank you for directing attention and putting the spotlight on two very deadly and insidious diseases. Malaria and Tuberculosis affect the health and wealth of nations and individuals. Especially in Africa, both are diseases of poverty and diseases that cause poverty. TB and malaria are the highest priorities for USAID in our work in infectious diseases.

I will speak briefly about the problem, burden and challenges of TB and then malaria, particularly in Africa and outline USAID efforts to battle these diseases.

TUBERCULOSIS

Although a cure for Tuberculosis has existed for more than half a century, the disease is often diagnosed or treated improperly, treatment doesn't reach those who need it, and so it continues to infect and kill some 2 million people every year, according to the WHO. Nearly 9 million people will develop TB during 2005.

Worldwide, the number of new TB cases increases by about 1 percent every year. The global resurgence of TB has been fueled by increasing HIV/AIDS prevalence, inadequate investments in public health system and emerging resistance to anti-TB drugs. Persistent poverty, crowded living conditions, and delayed diagnosis and treatment contribute to transmission of the disease.

TB threatens the poorest and most marginalized groups, disrupts the social fabric of society, and slows or undermines gains in economic development. An overwhelming 98% of the 2 million annual TB deaths—and 95% of the new TB cases

each year—occur in developing countries. On average, TB causes three to four months of lost work time and lost earnings of 20—30 percent of household income. For families of persons who die from the disease, the impact of TB is even greater as about 15 years of income is lost due to premature death. In developing countries, the impact of TB on the family is even more important as TB generally afflicts the most economically active segment of the population between the ages of 15 and 54.

In 2004 TB killed nearly 2 million men, women and children worldwide. The good news is that, thanks to better methods of controlling the disease, the global number of deaths is starting to fall. The bad news is that the TB problem is worsening in sub-Saharan Africa, where HIV rates are high. Tuberculosis and HIV feed off each other: they are entwined in a deadly co-epidemic which we must confront by succeeding in expanding TB treatment in African countries in the same way as China, India, Indonesia, and the Philippines have done. Globally, death rates have fallen by 2.5% between 2002 and 2003; and when HIV-positive TB patients are excluded, death rates have fallen by 3.5% illustrating the deadly combination of these two diseases. According to the latest WHO report on TB, of the 15 countries with the highest TB incidence rates, 12 are in Africa.

Of the 1.7 million annual deaths due to TB, about 13% are co-infected with HIV. But almost 1.5 million however, die from TB alone. While it is absolutely necessary to address both the TB and HIV epidemics together and to address the co-infection issues head on, it is not enough to only deal with co-infection—even in Africa where the TB/HIV burden is highest. Expansion and strengthening of the DOTS, the WHO recommended strategy for TB control, remains the cornerstone for effective TB control in all settings. .

We are making progress in much of the world and the Millennium Development Goal (MDG) to halt and reverse the incidence of TB is within our reach. The World Health Organization reported this March that levels of TB have dropped by nearly a quarter worldwide since 1990. The key to this success has been the DOTS strategy which is now in use in 182 countries. DOTS is a cost-effective approach with high cure rates even in poor countries. In less than a decade, more than 17 million TB patients were treated under DOTS. Detection of TB is increasing, in USAID assisted countries and worldwide, and DOTS programs have nearly reached the global target of 85% for treatment success.

USAID programs are making an important contribution to these results. Our programs support the expansion and strengthening of DOTS, and training of doctors, nurses and lab technicians. We provide lab equipment and supplies, help strengthen laboratory quality assurance, and support program monitoring and evaluation and information and communication campaigns to educate communities about TB.

Multi-drug resistant (MDR) TB is a serious problem. Since the beginning of the global anti-TB drug resistance surveillance project in 1994, 49% of new TB patients and 21 countries or settings in Africa have been surveyed. TB drug resistance is of low magnitude—below 3%—in the region. However, one of the challenges in Africa is a lack of information about TB drug resistance. Only 3 countries or settings have trend data on anti-TB drug resistance—Botswana, Mpumalanga province in South Africa, and Sierra Leone. Among these, the rate of MDR TB in Botswana increased from 1.2 in 1999 to 2.7% in 2002, and warrants continued surveillance. In Mpumalanga province of South Africa, the rate of MDR TB increased from 2.5% in 1997 to 4% in 2001. To help address this problem, USAID is providing assistance to expand and strengthen DOTS in this South African province. To address the gap in TB drug resistance information, continued investments in DOTS, including laboratory strengthening and training of personnel, are needed.

Multi-drug resistant (MDR) TB is a serious problem in some countries. Since the beginning of the global anti-TB drug resistance surveillance project in 1994, 49% of new TB patients and 21 countries or settings in Africa have been surveyed. TB drug resistance is of low magnitude—below 3%—in the region. However, one of the challenges in Africa is a lack of information about TB drug resistance. Only 3 countries or settings have trend data on anti-TB drug resistance—Botswana, Mpumalanga province in South Africa, and Sierra Leone. Among these, the rate of MDR TB in Botswana increased from 1.2 in 1999 to 2.7% in 2002, and warrants continued surveillance. In Mpumalanga province of South Africa, the rate of MDR TB increased from 2.5% in 1997 to 4% in 2001. To help address this problem, USAID is providing assistance to expand and strengthen DOTS in this South African province. To address the gap in TB drug resistance information, continued investments in DOTS, including laboratory strengthening and training of personnel, are needed.

But DOTS programs are straining under the pressure, especially in sub-saharan Africa where TB cases continue to increase due to HIV/AIDS, and where limited numbers of health workers and inadequate health facility networks create obstacles to care, especially for the poorest and most vulnerable. This means that too often

TB sufferers are not found in time; or if they are, they cannot be supervised through their treatment. We must do more to find TB patients earlier, and to treat them effectively when we do.

Engaging the private sector is one approach to addressing these constraints. In addition to working with Ministries of Health, USAID works with the private sector to improve diagnostic capacity and to increase access to quality TB treatment through initiatives called Public-Private Mix. Our efforts are paying off. In addition to working with Ministries of Health, USAID is works with and . Over 40 Public-Private Mix (PPM) DOTS pilot projects are underway in 14 countries, including several countries in Africa. These projects include individual private providers, as well as non-governmental organizations and Private Voluntary Organizations (PVOs). Treatment success rates in the PPM pilots are at or above the global target of 85% in most pilot sites, and the PPM sites have demonstrated increases in case detection of new TBsmear positive cases between 14%—61% due to private sector referrals to DOTS programs or diagnosis and reporting of cases in PPM sites. These PPM activities focus on the local level and engage private sector providers and health clinics, workplace clinics, pharmacies and NGOs in fighting the disease.

USAID is the leading bilateral donor in TB supporting the global expansion and strengthening of DOTS. In addition to supporting DOTS expansion in nearly 40 countries, USAID provides funding to the Global Fund to Fight AIDS, TB and Malaria (GF), and The Global TB Drug Facility (GDF) which provides grants for TB drugs to countries in need. We support advocacy, and research on new drugs and diagnostics. We also provide technical support to the GDF to help countries to strengthen management of TB drugs—this is absolutely crucial to ensure that drugs don't sit in a port, but instead reach the patient.

Increased funding for TB and new mechanisms are making a difference. The Global Fund has committed approximately $425,000,000 to the battle against TB. The Global TB Drug Facility, part of the global Stop TB Partnership, has effectively tackled the challenge of irregular and poor quality TB drugs. Since its inception in 2001, GDF grants, as well as the GDF procurement service has provided TB drugs for over 3.5 million patients, and the GDF has helped reduce the price of the TB medicines by about 30 percent, to approximately $12.00 per treatment regimen.

Twenty-five African countries have been approved for 2-year TB grants totally $109,330,269 in four rounds of grants awarded by the Global Fund. The total 5-year maximum for these grants is $223,148,330. In addition, three countries—Rwanda, South Africa and Tanzania—have been approved for HIV/TB 2-year grants totaling $81,869,831. The 5-year maximum for these grants is $269,060,932. USAID works closely with the Global Fund. Our missions participate in the Country Coordinating Mechanisms, assist with grant proposal writing, and help countries prepare implementation and monitoring and evaluation plans for these grants. Through USAID partners such as the TB Coalition for Technical Assistance, PATH and others, technical assistance, capacity building and monitoring and evaluation are provided to help the grant-recipient countries to effectively implement and manage Global Fund grant-funded programs and activities.

The main challenge now is to strengthen the systems that deliver public health services by improving methods of controlling TB, especially in Africa where we must fight HIV and TB together. TB is the leading cause of death worldwide for persons living with AIDS, therefore we must ensure that all HIV-infected persons have access to prompt TB care. This means offering HIV testing and where possible antiretroviral drugs to TB patients—while at the same time screening those infected with HIV for tuberculosis, and providing them effective TB treatment. We must move forward on expanding TB/HIV programs—and USAID is giving priority to this in our TB programs.

USAID currently supports programs to expand and strengthen DOTS in eleven African countries (Angola, Democratic Republic of Congo, Ethiopia, Ghana, Kenya, Nigeria, South Africa, Uganda, Malawi, Senegal, and Sudan).

This year USAID is beginning new assistance to the national Tuberculosis (TB) programs in Mozambique, Namibia, Tanzania, and Zambia. As all four countries are focus countries for The President's Emergency Plan for HIV/AIDS, the new TB resources will be used to strengthen DOTS programs and will complement funding for TB and HIV co-infection activities that are supported by the President's Emergency Plan.

USAID is committed to working with these important partners and others I will mention later to turn the tide against malaria, TB and other infectious diseases.

If we are to eliminate this virulent killer, not only must we remain vigilant, we must make continued commitments and investment so that hard-to-reach patients in Africa that are most seriously affected by this disease have an improved chance to live and contribute to society.

We believe that we have the means to beat TB. Despite their limitations, our existing tools have enabled us to increase the number of TB cases being found and cured each year. And our increased investment in research and development offers the promise of new drugs, diagnostics and vaccines that can revolutionize TB control and eventually eliminate the disease as a threat to public health.

There was a time when the principal obstacle to TB control in developing countries was access to drugs. But this is no longer a valid reason or excuse. We must continue to strengthen laboratories to diagnose TB, train more health workers, mobilize communities, and to involve all providers in DOTS. And in Africa in particular, we must expand and scale up measures to address TB and HIV/AIDS coinfection.

MALARIA

Malaria deaths increased during the 1980s and early 1990s corresponding with treatment failures related to drug resistance. In response, the global community worked with African countries to change to more effective malaria drugs. At the same time, USAID funded research on options for prevention that led to the development of insecticide treated nets as an effective means to get insecticides into peoples homes and tested the safety and efficacy of an extract of Artemisia annua, or wormwood plant to create an extremely effective new Artemisinin-based combination treatment.

The U.S. Agency for International Development's programs are making an impact—under five mortality rates are starting to decline in several African countries where malaria interventions have been put to work. Insecticide treated nets are now being used by millions of families throughout Africa. Effective drugs will be increasingly available.

COMPREHENSIVE STRATEGY

USAID has in place a comprehensive strategy to battle malaria including, prevention, treatment, and malaria in pregnancy. This strategy also includes special efforts focusing on malaria in complex emergency settings. USAID programs for malaria control are based on a combination of internationally-agreed priority interventions and country-level needs for achieving the greatest public health impact, most importantly, the reduction of most of the deaths.

They are:

- Prompt and Effective Treatment with an anti-malarial drug within 24 hours of onset of fever;
- Prevention of malaria primarily through the use of insecticides—treated mosquito nets (ITNs) targeted to young children and pregnant women and spraying of homes;
- Provision of Intermittent Preventive Therapy (IPT) for pregnant women as a part of standard ante-natal services.

Each of these interventions is backed by solid evidence of effectiveness under program conditions in reducing the sickness and death from malaria, especially in Africa. The Abuja Targets, set at exceeding 60% coverage for each, were agreed upon by the Heads of State of African countries in 1999, and are the basis for international malaria control efforts in Africa..

PREVENTION OF MALARIA

The most effective way to prevent malaria is through the selective use of insecticides that kill the malaria transmitting mosquito. The international community needs to move aggressively to ensure their widest possible use to protect vulnerable populations from malaria. There are two options for getting insecticides into the homes of those most at risk: indoor residual spraying (IRS) and insecticide treated nets (ITNs). USAID supports the use of both IRS and ITNs. The real challenge is about getting the insecticide where it can do the most good to protect young children and pregnant women to save as many lives as possible. The choice of which intervention to use should be driven by local conditions and needs. There are 12 insecticides approved by the WHO for indoor spraying, one of which is DDT.

INDOOR RESIDUAL SPRAYING

IRS is the organized, timely spraying of an insecticide on the inside walls of houses. It is designed to interrupt malaria transmission by killing adult female mosquitoes when they enter houses and rest on the walls after feeding, but before they can transmit the infection to another person.

USAID supports IRS and we are working with our missions to make sure there are no barriers to supporting if appropriate in that particular setting. In countries in which circumstances support the use of IRS (including DDT), USAID has funded support to malaria control programs using DDT in Eritrea, Zambia, Ethiopia and Madagascar.

The IRS campaign in portions of Zambia, the (Copper Belt) continues to bear good and encouraging results and USAD/Zambia, the largest contributor to the malaria program, continuing to provide crucial support in both financial as well as technical support in the fight against malaria.

There is strong technical consensus that IRS is best suited for areas of unstable malaria, epidemic prone malaria (especially in Southern Africa and in the Horn of Africa), in urban settings when local transmission of malaria is well documented, and in refugee camps. In each of these settings IRS has important advantages: it has rapid and reliable short-term impact and can be targeted to communities at highest risk. IRS is, however, relatively demanding in terms of the logistics, infrastructure, skills, planning systems and coverage levels that are needed for a successful and effective operation. Nevertheless, such systems have been maintained successfully and effectively in some African countries, especially where there are large populations exposed to unstable malaria.

ITNS

Soaking bednets with insecticides has been shown extremely effective in protecting people from malaria and can be distributed to the most rural and most vulnerable populations in areas like West Africa and in rural villages where most deaths occur.

By consistently sleeping under an ITN, severe malaria has been shown to decrease by 45%, reduce premature births by 42% and cut all-cause child mortality by 17%–63 %. In most high-risk African settings, ITNs are unquestionably the most effective way that families can protect themselves from malaria.

ITNs can be deployed now in the desperately poor countries in Africa where malaria-related mortality is highest and can be put into the hands of parents who want to protect their children. As a consequence there is a strong international consensus that ITNs, particularly in these rural African settings with a high malaria burden, are the best primary prevention intervention. This is the reason USAID has constructed a prevention program that strongly emphasizes the use of ITNs.

FREE NETS TO THOSE MOST IN NEED

USAID promotes targeting free or heavily subsidized ITNs for the most vulnerable (pregnant women and children under five years) and poorest populations—thus ensuring economics are not a barrier to net ownership. This evidence documenting how the use of bednets effectively protects against malaria is based on CDC field trials supported by USAID.

It is important that this targeted distribution of subsidized ITNs be combined with expanding commercial market distribution to develop systems for ensuring a commitment to the long-term availability of ITNs. Thus USAID supports expanding commercial market distribution, developing new technologies—especially in the area of long-lasting ITNs, and, the growing of ITN production capacity—to ensure adequate supplies of affordable and quality ITNs. There is recent evidence from countries where this combined approach of commercial marketing and targeted subsidies is in play that clearly demonstrates that household coverage with bednets is equally distributed across the socio-economic profile—from the poorest to the wealthiest families.

Recent data from several countries show dramatic increases in use of ITNs: ITN coverage increased from 11% to 43% in Senegal, 9% to 40% in Zambia, 0% to 21% in Ghana, and within the past year, 10% of Nigeria is now covered by an ITN—that is over 10 million people. In Tanzania and Malawi, UNICEF also has reported dramatic increases in ITN coverage. In all these cases, surveys point to a significant proportion of the nets being used by the primary target groups of children under five and pregnant women. There is equity in coverage across socio-economic strata.

Further, new technologies now provide long-lasting nets and treatments that remove the necessity for retreatment. The increasing availability of long-lasting insecticide treated nets (LLINs) which have an effective lifespan of about four years without the need for retreatment, will remove this requirement altogether.

These technical developments, the product of committed commercial sector engagement with Roll Back Malaria partners, render nets even more cost-effective that before: more affordable, more easily used, and more effective. ITNs also have

an additional advantage. Studies show some protection of children who live nearby a net, as opposed to IRS where there is no added protection.

COMMERCIAL PARTNERSHIPS TO BUILD SUSTAINABILITY

ITNs can be delivered through a variety of channels—public sector, NGOs, community groups, and the commercial sector—and can be readily added to existing services, such as antenatal services, or immunization programs. For this reason, ITNs are generally thought to be a very practical and effective means for protecting the large and dispersed populations of highly endemic malaria countries. ITNs have also been demonstrated to be highly deployable in rural Africa.

USAID has developed innovative models for the delivery of highly subsidized or free ITNs in collaboration with national malaria control programs in Ghana, Senegal and Zambia, as well as UNICEF, DfID, IFRC, NGOs and private sector partners such as ExxonMobil. With UNICEF this involves delivery of subsidized ITNs linked to routine immunization; with the Red Cross, ITNs are provided at no cost as part of targeted measles campaigns, and with ExxonMobil, the nets are delivered via a heavily subsidized voucher program through antenatal clinics.

USAID also partners with 13 major commercial firms (representing over 80 percent of the global capacity to produce and distribute ITNs) called NetMark. It is an innovative program that is working to share the risks of developing ITN markets, to identify and reduce barriers to effective engagement of the commercial sector, and to create demand, thereby expanding the availability of affordable nets. In five African nations, the program has helped eliminate taxes and tariffs. Expansion is scheduled to occur in several African countries, including possibly Kenya, Tanzania, South Africa, Ethiopia, Uganda and Malawi. This effort, joined with that of the many Roll Back Malaria partners to scale-up ITN access and use throughout Africa, can reduce malaria deaths by one million annually.

We hope that this successful cooperation with the commercial sector for insecticide-treated netting will serve as a model for future cooperation with the commercial sector in other parts of the world and with other health related products.

USAID is investing in building the capacity of African distributors and their suppliers to distribute and promote ITNs on a national scale. Strategic investments are made to support companies willing to spend its own money to expand through a matching fund scheme, while generic behavior change communication campaigns create demand on a The main barriers to scale up with ITNs have been changing residents' attitudes and behavior, cost of the nets, and limited distribution systems. To overcome these barriers, USAID is supporting targeted distribution of free or highly subsidized ITNs to children under 5 and pregnant women, extensive social marketing efforts and is working closely with net manufacturers and distributors in many African countries. Such practice was unknown to most rural African populations until the late 1990s.

As a consequence of these efforts we are on a trajectory to provide more than three million ITNs in 2004. USAID anticipates that sales of ITNs in seven target countries in 2005 will at least double and could reach seven million.

ARTEMISININ COMBINATION TREATMENT (ACT)

Until recently drugs like chloroquine, proguanil, and doxycycline cured the disease. But drug-resistant strains emerged, lowering the effect of these drugs. As drug resistance increases, the choice of first- and second-line drugs for malaria treatment has become much more difficult. Only a limited number of alternative drugs are available and there is little economic incentive for new drug discovery and development, given its high cost and the fact that malaria predominantly affects the world's poorest nations. Furthermore, in many malarious areas, a majority of the population does not have ready access to malaria treatment and those drugs that are available may be of substandard quality.

Since 1998, we have backed safety and efficacy testing of artemisinin combination treatment (ACT) in Africa. ACT is a three-day treatment made from the extract of Artemisia annua, or wormwood, a plant that until recently grew only in Vietnam and China. Combining artemisinin with another drug also means that there are two modes of acting, so if 95 percent of the infection is cleared with the artemisinin, the rest is taken care of by the other drug.

Since 2001, 40 countries, including 20 African nations, have switched from old drugs to ACT. An estimated 15 million malaria cases were treated with the drug in 2003, and demand for ACT will rise to 150 million treatments by 2007. But supply of this drug is limited. This will change later this year, when, because of a USAID/WHO parntnership with agricultural producers in Africa, African-grown artemisinin hits the market. USAID is working with the Global Fund to make fund-

ing available for ACTs and working with 25 countries in Africa to complete the legwork to roll-out ACTs.

Worldwide demand for artemisinin and its derivatives is expected to increase to 150 million treatments (up from 50 treatments in 2004). This forecasted increase has to-date outstripped the worldwide production capacity for ACTs leading to shortfalls in supplies. In response, USAID is supporting efforts to increase the cultivation in east Africa of Artemisia annua, the plant from which artemisinin is extracted, to increase availability of the raw product.

Artemisia annua has been successfully grown on both an experimental and commercial basis in both Kenya and Tanzania. Through the World Health Organization, USAID entered into an agreement with TechnoServe, an east-African agricultural concern to increase agricultural production in these countries.

In January, USAID helped plant 450 hectares of *Artemisia annua* in Kenya. And this month, another 450 hectares of the life-saving plant are taking root in Tanzania. Diversifying the location where the plant is grown will allow more drugs to be dispatched around the world faster. Because of the rich soil and warm climate, the African plant produces as much as four times more extract than its Asian sister, treating far more cases.

Through cultivation of the annual herb Artemisia annua, African farmers and estates can make a significant contribution to the worldwide supply of artemisinin.

USAID is presently working with 25 Global Fund recipient countries to prepare detailed plans for the introduction of ACT over the next year. Introducing artemisinin to Africa we will not only save millions of lives, but will also provide employment and bring about better opportunities for thousands of farmers. The new crop has been welcomed by Kenyan farmers, particularly coffee-growers, who have seen the value of their once prized commodity plummet to all-time lows in recent years. It will also provide some competition to the market and hopefully lead to lower prices.

USAID is strengthening national drug regulatory authorities. The aim is to improve the manufacturing of pharmaceuticals through good manufacturing practices, including drug quality control in national malaria programs.

USAID, in addition, is actively working with pharmaceutical companies to upgrade their ACT production capacity in order to increase the pool of companies manufacturing WHO approved ACTs. By 2006 it is expected that worldwide supplies of ACTs will be in line with demand. In the interim, strategic targeting of ACTs will be required to ensure that those countries with high levels of drug resistance have adequate drug supplies.

PREVENTION OF MALARIA IN PREGNANCY

Each year, more than 30 million African women become pregnant in malaria-endemic areas and are at risk for Plasmodium falciparum malaria infection during pregnancy. Most women live in areas with year-round malaria transmission, where the infection during pregnancy leads to anemia in the mother and the presence of parasites in the placenta. The resulting impairment of fetal nutrition contributing to low birth weight (LBW) is a leading cause of young infant deaths and development in Africa. HIV infection diminishes even more a pregnant woman's ability to control malaria infections. The prevalence and intensity of malaria infection during pregnancy is higher in women who are HIV-infected. Women with HIV infection are more likely to have symptomatic infections and to have an increased risk for malaria-associated adverse birth outcomes.

WHO has recommended intermittent preventive treatment (IPT) using the antimalarial drug, sulfadoxine-pyrimethamine (SP), as the preferred approach to reduce the adverse consequences of malaria during pregnancy in areas with year-round transmission. Since more than 70% of pregnant women in Africa attend antenatal clinics, Provision of safe and effective antimalarial drugs in treatment doses can be easily linked to antenatal clinic visits. The potential of IPT to attain high levels of program coverage and its benefit in reducing maternal anemia and LBW makes it a preferred strategy in sub-Saharan Africa. In HIV-negative pregnant women, two doses of IPT provide adequate protection, but a minimum of three doses appears to be necessary in HIV positive women.

USAID played a key role in supporting the original studies in Africa that documented the efficacy of IPT in preventing the impact of malaria on both HIV positive and HIV negative pregnant women and their babies. Many countries have already changed their policies to incorporate IPT. Currently, through a coalition of partners, USAID is assisting ministries of health in about 10 African countries to implement IPT and distribute ITNs as part of a package of health interventions at the antenatal clinic level. Over the last year this technical assistance has contributed

significantly to revision of outdated policies in Senegal, Ghana, Rwanda, and Zambia and to increased implementation of revised policies in DRC, Tanzania, and Kenya. Among women attending antenatal services in Tanzania, delivery of intermittent preventive therapy has increased from below 30 percent to over 60 percent.

EXPANDING GLOBAL NETWORK

No one agency can do it all. The international efforts to fight malaria and TB are largely coordinated global partnerships that includes leaders from across the world, health institutions, the World Health Organization (WHO), UNICEF, World Bank, UNDP, multi-lateral agencies, international, national and local NGOs, and the private sector. We are a key partners as well in this Roll Back Malaria Partnership and the Global STOP TB Partnership.

USAID also has developed strong partnerships with many companies, bringing in private dollar side by side to support public programs. USAID is committed to reaching out beyond our traditional partners to find able and creative organizations, particularly those that are faith-based and community-based.

And with so many new partners, the coordination of our efforts becomes even more critical. This is as true among the U.S. government agencies as it is among our international partners, including the new Global Fund. Coordination efforts must occur at two levels: at headquarters and in the countries we are assisting. These actors are fulfilling unique roles—roles only they can perform due to their expertise, positions and responsibilities.

- USAID, HHS and CDC also work closely to fight these public health threats, and are coordinating with many others in the Roll Back Malaria Partnership and the Global STOP TB Partnership. USAID conducts annual planning meetings with the CDC and has an Interagency Agreement (IAA) with CDC for specific malaria and TB prevention and control activities. In Stop TB—the Agency is a member of the Partnership's coordinating board and USAID technical personnel are members of all STOP TB technical working groups. USAID's priorities are consistent with those of Stop TB. These efforts are well organized and coordinated and benefit from country and leading technical agency.
- USAID missions work closely with the Global Fund to Fight AIDS, TB and Malaria (GFATM) by leveraging mission funded programs with the substantial funding provided by the GFATM. Through the *Global Fund*, USAID and international partners have come together to combine financial, technical, management, and other expertise to reduce the public health impact of malaria and TB. Over the past three years, the U.S. government has contributed $623 million to the Global Fund, and has appropriated up to $547 million this year. We committed through our board participation and technical review panel in country technical assistance helping the GF succeed in HIV/AIDS, TB and malaria.
- Research institutions and pharmaceutical companies can develop improved treatments and interventions to help protect us against malaria and its impacts.
- Community- and faith-based organizations and other NGOs extend deeply into many of the most rural areas, reaching societies and cultures to ensure health care services and malaria treatments and interventions get to hard-to-reach populations.
- National governments have especially important roles to play with specific, attainable steps to reducing the impacts of malaria—steps that only they can take. The international donor community, in partnership with developing country partners, can ensure that technical and financial resources are allocated where they will be most effective.

USAID is focusing on the best ways to save the lives of millions from malaria's grip. Too many lives are at stake. Collectively, we must gather our will and our resources to stop the spread of this deadly disease.

Mr. SMITH. Thank you very much, Mr. Miller.

Let me just begin the questioning first by noting that I am encouraged that PEPFAR says that it will provide and enhance priority TB. Providing TB treatment for those co-infected with both diseases can extend the life of an HIV-positive person, as we know, from weeks to years.

However, as we all know, TB is transmitted via the air and it is especially rampant among the poor. I wonder perhaps, Dr. Dybul, you could tell us: How is PEPFAR supporting scale-up of DOTS TB programs overall in target countries so that TB treatment services are reaching the very poor?

Dr. DYBUL. Thank you, Mr. Chairman. The focus of the Emergency Plan's resources are on co-infected individuals, rather than on the general population.

This, however, does have, we believe, a significant affect on the general population. I will give you one specific example. In a rural clinic in Toruor I visited recently, the United States supported placement of an X-ray machine for the Emergency Plan, because you need an X-ray machine to diagnose pneumonia, tuberculosis and other things in HIV-infected people.

While that machine is not being used for HIV-infected people, it is used for the general population, including the diagnosis of tuberculosis and we support the technician who monitors all of that and the ongoing maintenance of the machine and also fix checks for broken bones and other things. So we are having an affect behind HIV-infected people.

The other affect is more direct. As we support TB therapy for HIV-infected people and people are coming up with novel approaches, such as a voucher system to refer someone from a TB clinic to TB–HIV clinic, where we can pay for the therapy, it frees up resources that can then be used for non-HIV-infected persons.

So our approach really is to focus on the HIV-infected individual and to use the local structure and the local structure in the countries we operate in is the DOTS system.

We actually believe there is tremendous synergy between our activities around tuberculosis and the World Health Organization. We recently had a good bilateral meeting with them and we are focusing on a couple of countries where we can rapidly expand HIV–TB therapy for these individuals.

So it is through a variety of mechanisms supporting the local DOTS system, but in our case focusing on HIV–TB infected persons.

Mr. SMITH. Let me just ask you, in looking at the Administration's request for 139 million for USAID's program to combat other infectious diseases, including TB and malaria, maybe Mr. Miller, you might want to tell us, this is less than what was provided last year. That sounds like it is OMB getting into the mix to me.

Can additional funds be used effectively to mitigate these diseases and hopefully cure people with them?

Mr. MILLER. Thank you, Mr. Chairman. The need is so great in Africa that it is almost hard to say that you couldn't identify some place to address greater need.

I will say that given a larger budget and funding constraints, these are never easy decisions. It shouldn't be taken as a reflection of what we think of our programs or how far we would like to advance them, and of course we are always grateful for your support.

Mr. SMITH. I appreciate that. We will be looking at that very carefully, because it seems to me that just straightlining would seem to be a cut, but going below last year it seems to be a true cut.

Let me also point out that you said that USAID is vigorously supporting the development of ACT drugs. Yet, stories persist that due to the higher cost of ACT, USAID is encouraging certain governments to purchase lower cost chloroquine and other related drugs.

You might recall, because I am sure you had to respond to it, this is part of a January 4 Lancet article. Is USAID still recommending use of chloroquine, and if so, why?

Mr. MILLER. No. We never recommend the use of ineffective drugs. There are some areas of Africa where fancidar is still effective. Given the fact that there actually is a supply problem with ACTs, until there is further production and availability of artemisinin, that is possible, and if fancidar can be used as an effective therapy in certain areas, we can do that. But no, we would never ever recommend that someone use a drug that doesn't work.

Mr. SMITH. Let me ask you with regards to the issue of DDT, which has obviously been very controversial. What are the pros and cons of the indoor spraying?

I know it is used in combination with the nets, which prove difficult for keeping a young child protected. It is the child under 5 that is most likely to die of all populations, perhaps as a result of an episode with malaria.

Young children move around and don't stay necessarily in one place. It seems to me that despite all the prodding, staying inside of the net might be difficult.

Can you speak to the pros and cons of DDT? What is the current state of thinking at USAID on that?

Mr. MILLER. Sure. Thank you. It is a good question, because we have heard a lot of discussions about it. I think one thing I want to say off the bat is it is not a question of nets versus spraying.

We have heard that argument brought to us in that form many times. Certainly the United States has supported spraying extensively in the past and USAID does support spraying, including DDT currently in some areas, particularly in emergency situations.

DDT is not the only insecticide we are talking about. In fact, I think it is one of 12 insecticides on the approved list by WHO, but it is not a question of whether we are for or against DDT.

There is no problem with DDT. It was used very effectively all over the world, sprayed directly in homes. I think the concern before in the 1970s was really with the scale of the agricultural spraying and the persistence of it in the food chain and the environment. That is not a concern for us.

The reason you have a focus on nets in Africa versus DDT or one of the other 12 insecticides used for spraying is really about the difficulty of spraying and what it would take to have a sustainable program in place.

There are points of debate on what it requires, but suffice to say that the challenges in most of Africa and the highly endemic areas is very great and if you have to spray and respray every 6 months a year, it is going to be very difficult to do.

I should also conclude by saying both are effective. Both are very effective, if used correctly. It is not a debate about effectiveness and I think even the proponents of increasing the use of DDT would

agree that nets are effective and they are going to get more effective as long lasting nets are made more available.

Mr. SMITH. Dr. Dybul, you would agree with that?

Dr. DYBUL. Yes. The link between tuberculosis and HIV is very clear. The link between malaria and HIV is a little less clear. Clear for, as you pointed out, children and pregnant women.

So that is where we concentrate our efforts, and we agree completely with Mr. Miller's comments that there are a variety of effective mechanisms. We employ the mechanisms that are accepted in the community and which are used in the community to get to those women and children and so we do agree.

Mr. SMITH. Could you tell us, Mr. Miller, where USAID is supporting the spraying? In what countries and to what extent is the budget earmarked or focused on that?

Mr. MILLER. I will tell you that I don't think we have an earmark. I think in five or six African countries——

Mr. SMITH. If you could provide that for the record?

Mr. MILLER. I'm sorry?

Mr. SMITH. Could you provide that for the record?

Mr. MILLER. I can.

Mr. SMITH. Please provide the names of the countries.

Mr. MILLER. There are five or six African countries who are supporting spraying. Also in emergency situations spraying indoors is very effective. I think USAID is supporting spraying in Burundi. We will get the exact countries.

Mr. SMITH. I would appreciate that. We will make it a part of the record.

Mr. MILLER. Sure.

[The information referred to follows:]

WRITTEN RESPONSE RECEIVED FROM MR. MICHAEL MILLER TO QUESTION ASKED DURING THE HEARING BY THE HONORABLE CHRISTOPHER H. SMITH

USAID SUPPORT FOR IRS

In the last fiscal year, USAID provided support for indoor residual spray programs in Eritrea, Zambia, Mozambique, Uganda, Kyrgystan, Angola, Liberia and Burundi. The latter three were part of humanitarian assistance efforts managed by the Office of Foreign Disaster Assistance. Support ranged from the purchase of insecticide and equipment in Kyrgrystan, to support for training, planning, implementation and monitoring and evaluation. Funding is not specifically earmarked for IRS—or for any other specific intervention. The level and specific nature of support is determined by the needs of a particular country and malaria control program, and by the funding available.

Mr. SMITH. Let me ask you about NGOs that are USAID supported that turn around and allegedly sell some of those products for higher amounts.

I saw a very disturbing article by Richard Tren called *USAID's Troubling Malaria Efforts*. It points out that the Population Services International, or PSI, in Madagascar, was charging for the nets some 200 percent what, to quote: "What the government could do it for." They were charging an inflated price. Is there any accuracy to those allegations?

Mr. MILLER. I don't know the specifics. I haven't read that article, but it is worth pointing out that USAID supports giving away nets free.

Mr. SMITH. Right.

Mr. MILLER. And USAID supports selling nets, depending on the situation. The key is really having a balance between equitability and sustainability and what that really means is if someone is too poor to afford a net, we will give them a net if we can.

If they can purchase the net and they can sustain a market, they can push that market and make that net available for others through purchase, we will do that as well.

Mr. SMITH. Is there any specific monitoring of the commodity above what individuals are able to pay?

Mr. MILLER. We can get specific monitoring information back to you, but certainly if anyone was exploiting their opportunity, it would not be looked on favorably.

[The information referred to follows:]

WRITTEN RESPONSE RECEIVED FROM MR. MICHAEL MILLER TO QUESTION ASKED DURING THE HEARING BY THE HONORABLE CHRISTOPHER H. SMITH

ITNS IN MADAGASCAR

We are unaware of details or calculations leading to the allegation that nets would be sold by PSI in Madagascar for "twice the price." The "twice the price" language most likely refers to the common practice of "cross-subsidization," in which full market-price goods are sold in urban area shops to those who can afford them, and the proceeds used to subsidize free or very low-cost nets for the rural poor. Segmenting the market in this manner increases the efficiency of subsidies, ensuring that more of the donor funds are directed to those in greatest need, the rural poor. This market segmentation also ensures that operating costs are available to sustain the ITN supply process, giving greater sustainability for the long-term.

With regard to prices of nets, it is USAID's policy that economics should never be a barrier to ITN use. USAID staff members carefully monitor programs and work closely with partners in each country to ensure that any nets purchased with USAID funds are distributed in a manner that works to reduce economic barriers to ITNs to the maximum extent possible. Market prices of ITNs are frequently checked as part of this on-going monitoring. Encouragingly, recent survey data from several countries, including Senegal, Ghana and Nigeria, show equitable increases in ITN usage across socio-economic strata. In Senegal for example, the percentage of poorest households that own an ITN increased from 6% in 2000 to 31% in 2004, while the percentage of richest households owning an ITN increased from 10% in 2000 to 34% in 2004.

Mr. SMITH. Dr. Dybul, let me ask you a question. Our second panel includes William Moeller, the President of American Biotech Laboratories. He has a very provocative set of recommendations regarding some of his products.

I would appreciate your response to that. He points out that it is a company that produced engineered metallic silver which created nano-sized particles in water-based products that have performed far beyond any of his expectations as antimicrobial agents against a staggering array of microorganisms, such as malaria, flesh-eating bacteria and E. coli.

He points out and says that in 2001, 12 bottles of their product was used by Dr. Ezechias from Rwanda on 11 children who were very, very sick with malaria and that after taking it, all 11 left his clinic alive and healthy.

Do you have any knowledge of this product? Its efficacy? According to the testimony, TB is also being looked at, but as he points out the information is preliminary, but while they are encouraged, they are not about to say anything definitive about it.

When I first read this and heard about this, I would have to put myself into the surprise category, like others perhaps who have seen it, but what is your take on it?

Dr. DYBUL. Thank you, Mr. Chairman. We are familiar with it now, as a result of this hearing. We noted who the other speakers were and found out what we could.

There are actually a variety of drugs being developed, and in development, for tuberculosis and malaria. Unlike my previous life, where I helped create guidelines, in this current program we are implementing a program and so we take the guidance from the World Health Organization, U.S. guidance, and fundamentally, the guidance within countries.

So once it has been deemed by scientific and advisory committees to be a recommended approach, we then implement. But we do not really get engaged in the Office of the Coordinator, because of the expertise and because we are an implementer, until it has reached that point.

If these drugs are recommended by the international community and by the national programs, we of course would move to implement them.

Mr. SMITH. I appreciate that.

Mr. Payne.

Mr. PAYNE. Thank you very much. I am just trying to, if either one of you get a picture of how the Global Fund, under Ambassador Tobias and the global AIDS, the U.S. program and the global AIDS fund, is there coordination or how do we interact with the Global Fund in general?

Dr. DYBUL. Thank you. There are a variety of mechanisms with which we work closely with the Global Fund. The Global Fund is an essential part of the strategy of the U.S. Government's effort to combat HIV/AIDS and tuberculosis and malaria, but both bilateral and multilateral approaches are essential to combatting this disease and we need everyone who is able to contribute to the fight.

Ambassador Tobias just assumed his seat this past week, actually, as the voting member on the board of the Global Fund and so he will now be intimately involved in all the proceedings of the Fund and we are very excited about that opportunity to deepen the relationship between our office and the Fund.

Prior to that, as you know, former Secretary Thompson had the seat as Chair of the Fund.

Another way we work very closely with the Fund is to remain in constant contact with them. As we had a bilateral meeting with the World Health Organization a couple of weeks ago, we had our bilateral with the Global Fund, where we run through country-by-country where we are doing activities, where they are doing activities and how we can work better together.

Actually, this works quite well on the ground. In a number of countries, for example in certain sites, the Global Fund will provide drugs, while we will provide the training and physicians and nurses and other activities in the same site. That is why when Ambassador Tobias and Dr. Feachem, along with the World Health Organization and UNAIDS announced the current results for the world, we showed where the Global Fund and the U.S. were actually supporting many similar individuals in the focus countries.

So we work very closely together at the country level, with the Global Fund and so these are the predominant means by which we work together, both at the higher level at the executive committee and the board of the Global Fund, but also in-country to ensure that our programs are working together, that there isn't duplication of effort, that in fact we are contributing to support the national strategies in the most effective way.

Mr. PAYNE. Thank you. There are 14 countries I think in the PEPFAR program, the President's program. Do we have a best practices? For example, the individual countries running the various programs, is there evaluations of what seems to be working well or what is not?

I know that there is a big difference in the rate of prevalence, at least for HIV and AIDS; some as high as close to 40 percent in Botswana and, you know, some as low as 2.5 percent in Guyana.

There is a grave difference; however, are we looking at mechanisms or ways that programs are being run and then trying to replicate them in the PEPFAR area?

Dr. DYBUL. Thank you very much. That is actually an extraordinarily important question and gets at the nature of the focus countries and why we have focus countries.

One approach would have been to spread $15 billion over the 100 countries in which we have bilateral programs. The decision was to focus in 15 countries—originally 14, a 15th was added—where the U.S. Government would commit to scale up under national strategies, full national, integrated prevention, treatment and care programs, precisely for the point you identified, to show models of lessons learned, how we can scale up from pilot projects to full national integrated prevention, treatment and care programs.

With the U.S. Government contributing about 50 percent of all donor contribution to HIV/AIDS, we are focusing this approach to show how others can then join the fight with similar mechanisms, both the Global Fund, World Bank and our own bilateral programs outside of the focus countries.

So that is a key aspect of what we do and, in fact, we are identifying key lessons learned for how you can scale up these programs with our partners under national strategies.

In approximately a month, we will have a conference in Ethiopia bringing all of our partners together to outline many of these lessons learned, both in an integrated approach for integrating network systems, gender issues, drug procurement systems, but also specifically around prevention, care and treatment, what are the lessons learned that we have so far to spread across the focus countries, but also across all of the nations.

Because the United States contributes 33 percent of the Global Fund, we have a strong interest just in making those dollars work, making the Global Fund work, because those are American taxpayer dollars as well, and so we want to expand these programs beyond the focus countries.

So your question really gets at the nature of the focus countries demonstrating full-scale upward prevention, care and treatment across a number of different spectrums with different prevalence rates, different drivers of the epidemic so that we can contribute to the global fight in many ways.

Mr. PAYNE. Thank you very much.

Administrator Miller, in regard to the manner in which the medical part of attempting to come up with medication, you know it seems that, and this is just your opinion, I know you are not a doctor, but malaria has been around for a long time and of course tuberculosis was just about eradicated in other parts of the world.

Therefore, I think when the prevalence returned in the United States, maybe about 10 or 15 years ago, there was very little streptomycin as a matter of fact, I think, which is the basic medication used in the combat of tuberculosis. There was none around, because there was not much of a need for it in the Western world.

I guess my question goes to the seemingly lack of research that has gone into trying to come up with a medication or some approach to eradicate malaria. Do you think that is basically because malaria is in countries where there are poorer people and, you know, you really don't have folks that are going to be able to pay for it too much?

I mean you know we find that pharmaceutical industries are businesses and they try to take on medicines that can be paid for, once they go through the research.

So do you think that there has been a lag in the interest of trying to find some way to better combat malaria and/or if the CDC or some Federal agencies or U.N. agencies could have money gathered to invest in a real serious move to try to come up with a way to combat malaria?

Mr. MILLER. Thank you. I agree with you. I think just on its face, it would seem that if a company who is engaged in research in a vaccine or a treatment doesn't have the underlying motive that it has to report to its shareholders, that it is doing what the shareholders expect it to do, it is hard.

There is no moral judgment in that. That is just the way companies have to operate.

With respect to malaria, that is where ACTs are very exciting. As I mentioned in my opening statement, they are really an ancient therapy.

It is putting them in combination with other therapies and getting them into people, of course, which is the big challenge, and what is also very exciting. There is a supply question. There is also a supply question about the plant from which it is derived, artemisia annua. It is grown primarily in China and Vietnam.

USAID is supporting a public/private partnership that actually has artemisia annua growing in Kenya and Tanzania now and we are looking to expand that.

We think ACTs offer the best chance to plug that hole, as I mentioned, that when other therapies fail, because malaria adapted to them, that we can come in with ACTs and in a big way positively affect a lot of people's lives.

Mr. PAYNE. Thank you very much.

Thank you, Mr. Chairman.

Mr. SMITH. Ms. McCollum.

Ms. MCCOLLUM. Thank you, Mr. Chair. I have two questions. We know that malaria can cause life threatening anemia, particularly in children and pregnant women. In severe cases, which is not infrequent, blood transfusions are required to save the patient's life.

Since both malaria and HIV are endemic in many African countries, ensuring a safe blood supply, in other words testing blood and counselling and having a laboratory capacity to do it fast is critical.

Outside of major urban areas, in regional and rural facilities, what are the strategies PEPFAR has engaged in and what are the outstanding needs and how serious of a problem do we have in ensuring safe blood?

That goes to a question when you were talking, too, about testing for HIV. We know there is not enough facilities testing even in the countries PEPFAR is in so that people are even aware of their status for HIV, let alone possibly for malaria.

Leading to the point of building critical infrastructure, I came across an article last week in the *Wall Street Journal* about a study requested by your office, sir, the State Department, to promote a global health service in which it was described as the Peace Corps to fight AIDS and other health needs.

I think that is a laudable goal, but I have concerns about the collapsing health care infrastructure in many African countries, and this is a serious impediment in combatting and treating malaria, tuberculosis, and AIDS.

More trained country health care workers are desperately needed. I must say I was shocked to read in this report that one of the proposals that is floating about is sending 150 physicians and other specialists to Africa for 2 years of service in exchange for a salary per person of $225,000.

To me, this proposal borders on possibly being outrageous. Why would we place American doctors, making $8,000, $9,000, $10,000 plus exorbitant overhead and support costs for people who don't even speak local languages, know little or nothing of local customs, next to African doctors making $100 to $200 per month?

It makes no sense and it doesn't, in my opinion, begin to meet the critical need for health care workers and enforcing health care workers in those countries to stay, remain and feel respected.

This proposal that I read about, and maybe the *Wall Street Journal* wasn't very accurate in describing it and I know you can clear that up, would cost supposedly around $100 million the first year.

Just think, and I often have, having traveled in parts of Africa, if we trained African health care workers, how many we could train for $100 million and keep them competitively employed in their own countries?

I am wondering what is our balance here in really looking into investing on a massive scale, investing in African citizens and community health workers and nurses and clinical offices, as well as doctors? To be true partners with us, co-equals in the battle against AIDS, along with some of our health care professionals, which would be on the ground.

By failing not to invest in Africans and treat them as the partners they deserve to be treated as, I don't see how we really come forward with a sustainable, long-term solution.

I am interested in hearing any comments you might want to share on that, because dollars are very, very scarce.

Dr. DYBUL. Thank you very much for those questions. I hope I get to each of the points you raised. One is a safe blood supply.

A safe blood supply is an essential piece of any prevention program for HIV/AIDS, and so in each of the focus countries, we have engaged on two levels. One is to provide technical assistance to build safe blood supplies and South Africa is a great example of a country, Botswana, that is in fact very far along in building a safe blood supply and we are trying to replicate that in each of the countries.

We are also directly supporting the governments, because blood banks and blood systems really need to be managed under the national strategy and under the national health care infrastructure, in part getting to your last point.

So we are both providing technical assistance, but also supporting the national blood bank, whether it be government or a subsidiary to the government, in each of the focus countries, with the goal being a completely safe blood supply by the end of the Emergency Plan.

You asked about counseling and testing in remote areas. We agree with you completely. On a variety of issues, counseling and testing is really one of the keys. It is the mechanism by which people enter care and treatment services.

We are actually now very focused on this as we are looking across where impediments are to implementing the Emergency Plan, because we will need to test tens and millions of people in remote areas and across these countries in order to care for 10 million and treat 2 million, as the President and Congress have instructed.

So we are fanning out with mobile units to get counseling and testing services out. We are targeting things like TB clinics, where there is a high incidence of co-infection or sexually-transmitted infection clinics, where there is a high incidence of co-infection, in order to get to those people who are infected.

This is actually being very successful, as policy negotiation with the countries around the nature of testing, the targeting of testing, but as a key focus for us as we are trying to achieve our goals.

Your last issue regarding the Institute of Medicine report is one that is important to us. We commissioned a report to look at different ways to enhance human resources. That doesn't mean that we will follow all of the recommendations of that report.

Our focus is your focus, which is to ensure that we are developing local capacity. You know in just the first 8 months of the Emergency Plan, we provided support to train more than 300,000 health care workers in the focus countries, and it is not just training.

Training alone won't get us there. We have to actually build the health network systems and that is not just training. It is providing the infrastructure, providing the resources. It is providing the monitoring and evaluation, logistical systems. It is ongoing training.

Weekend courses just aren't going to be enough, but the goal is exactly what you said. The only thing I would disagree on is co-equals. We are not co-equal to the Africans or the Haitians. They are far above us. This is their epidemic. This is their national strategy. This is their fight.

We are there to support their fight, but we are not co-equals with them. We should not be doing the hands-on work. We should be working with them to develop their national strategies and their national plans in all aspects of the health care, and by doing that, we will not only affect the HIV/AIDS epidemic, we will affect the health care systems overall.

So our goal is the same as yours. There are different mechanisms and we need to get care and treatment out there. So we will look at the suggestions, but we agree with you completely that the goal is to develop those network systems for health care in the countries run by people from those countries.

Mr. SMITH. Mr. Sherman.

Mr. SHERMAN. Mr. Chair, I just want to thank you for holding these important hearings.

Mr. SMITH. Thank you. Let me just ask a few follow up questions, if I could, and one or two additional questions.

Again, I talked about this a little bit earlier, but the DOTS strategy, my understanding is, reaches only about a third of the people with TB and I think you have so stated.

However, the DOTS strategy can produce cure rates of up to 95 percent for about $12. How are we ramping up that? Increasing our focusing on that?

You know it seems to me that best practices and best utilization of scarce resources would require additional prioritization of that.

Dr. DYBUL. I can answer part and then maybe Mr. Miller could answer the other part. Our part is for HIV/AIDS co-infected individuals. Again, we support the local strategy to expand care services for HIV-infected people, which in the countries we operate in, is the DOTS strategy, which we believe in and needs to be expanded.

Again, people are coming up with novel approaches. Some are voucher systems where in the DOTS program they will get a voucher, which the Emergency Plan will pay for, but it helps support the DOTS system.

So people are coming up with novel approaches and we are hoping, as Mr. Payne said, to get some good lessons learned out of this that we can spread throughout the countries and throughout the world.

Our focus is on expanding those programs within HIV-infected individuals and then, if you would like, maybe Mr. Miller could talk about beyond.

Mr. MILLER. Sure. I would say in general expanding DOTs and strengthening DOTS is really the basis for our program. Seventy-five percent of our spending on tuberculosis at USAID goes to just that.

I think it is important to understand how it is virtually a global consensus that this is the right strategy to undertake.

That makes things a bit easier for us and we can use our relative advantage in certain ways to come in and help strengthen systems. The trick is, we have got to get people diagnosed, get them into the system and get them cured. Top priority.

Ms. MCCOLLUM. Mr. Chair, on that point, if you would yield?

How many of the centers where we have people coming in for tuberculosis are we testing for HIV when they are in there? Because

we have the laboratory facilities right there. We have clinicians right there. In some countries where there is stigma, that removes that.

Are we testing for HIV in those clinics and conversely, when someone comes in to an HIV clinic, are we testing for tuberculosis and malaria?

Thank you, Mr. Chair.

Dr. DYBUL. Those are excellent points and that really is what we are trying to focus on around both of those issues, the care and treatment and also the testing.

I can't give you a number of sites where we are doing testing for HIV in the tuberculosis sites. They don't always do the testing there. Sometimes they refer them to other sites, but the goal, as I mentioned, is in fact if we could, and this is the formal guidance we have given to the countries, test every person who has tuberculosis for HIV/AIDS in the focus countries and conversely, make sure that we are diagnosing tuberculosis in all HIV-infected persons.

In the first 8 months of the Emergency Plan, we did support care and treatment for 240,000 co-infected persons and we are 7 months beyond that now. We have certainly grown much past those.

We also are developing the reporting structure so we can do a better job of identifying those, and as a result of our bilateral activity with the World Health Organization, we are actually concentrating on Ethiopia and Kenya, to see where we can expand our programs together as models.

I can't give you a specific number of the sites. I can give you specifics of how many we are supporting, in terms of co-infection treatment and care and we are trying to develop the monitoring and evaluation systems to be able to provide that information as we go along.

Mr. SMITH. Let me ask a question of Mr. Miller. You probably have seen Roger Bate and Benjamin Schwab's analysis from American Enterprise Institute. It says that USAID policy fails to control malaria and they make a number of critical and in some cases scathing assessments, but one of those they make is repeated in a op-ed that Roger Bate wrote for the *Examiner*. It is that perhaps its greatest shortcoming as an international development agency is that USAID embraces a contracting structure that keeps money inside the Beltway and hands out big contracts to big development firms.

They point out in this analysis that that leads to a very capable group of lobbyists to lobby Congress so that this flow continues. Because of this, best practices aren't necessarily achieved or realized and the person on the ground with malaria doesn't necessarily get treated.

How do you respond to this report? Have you seen it?

Mr. MILLER. I have seen the report. I have not read it. This is the one that I think was released yesterday.

Mr. SMITH. Yes, it was.

Mr. MILLER. The op-ed I have seen. I know that some of our folks are looking at the report in some more detail. It is fairly long and I know we do have some concerns with some of the conclusions in the report.

Certainly I can say right off the bat that the characterization that our malaria programs are underwriting lobbyists and jobs here inside the Beltway is simply wrong.

As with every program we design and every program we field, the bottom line is to save the most lives possible, not employ the most number of people possible, and that is true here. It is simply not an accurate characterization.

Maybe I should also say almost all of our assistance programs are undertaken by partners, cooperating agencies. It is not like the USAID of old, say during the Vietnam War, where there were thousands of actual USAID employees out there implementing programs.

We run competitions. We give grants or assign contracts for private groups of various types to implement our programs and I would not characterize any of them as lobbyists or in it for the money. It is really a much different picture.

Mr. SMITH. Is there an effort being made to break out more of our contracts? I remember that when I first got here 25 years ago, one of the successful changes that was made in DoD procurement policy was to ensure that smaller firms could provide a product, even if they weren't necessarily an ace at writing grant requests and did not have the inside track. There is a saying that he who wears the specs gets the grant, meaning that when you get awarded additional points for longevity of the business, you sometimes crowd out others, who might otherwise have a very innovative approach.

Is there an attempt being made within USAID to try to find these gems out there of NGOs and others that could provide?

Mr. MILLER. Yes, there is. You are exactly right. The people who are good at it become better at it and it reinforces itself and of course that is just the nature of competing and getting better.

In terms of diversifying our partners, getting small partners who can't write the best proposals, don't know how to approach the Federal Government, or have never responded to a solicitation and done a concept paper, yes, those are the exact people we are looking at.

In PEPFAR and in our other programs, including malaria and TB and other infectious disease, we do have specific programs called new partners programs. Generically speaking, these programs are targeted toward new partners.

It provides opportunities to get people in and tell them exactly what they will face in a competition. It shows them the kinds of things they will see in a pre-competition audit. It tells them the things they need to know and how to compete. This is how you get in the game and we always view that as very positive.

The more people competing, the better proposals you are going to get and the better implementation you are going to get.

Mr. SMITH. Is that message being perceived and really put out to the USAID people in the field so that they realize that there are indigenous NGOs that could provide this, but they don't have a clue how to perhaps approach it?

Mr. MILLER. I have been in USAID for a year so it is hard for me to say personally what has happened historically, but yes, it is

and it is increasingly an emphasis we have in the Global Health Bureau.

I would say within the Administration in general and certainly within PEPFAR, for which I will turn to Dr. Dybul, but he and I have been working on something specifically aimed at addressing that issue, pulling in new partners. We think they offer valuable opportunities and valuable skills that may otherwise be idle.

Yes. So the word is getting out and the programs are moving forward.

Mr. PAYNE. Mr. Chairman, would you yield on that?

Mr. SMITH. Sure.

Mr. PAYNE. I would just like to support the Chairman's questioning. I did not see that article or the report and my staff is going to get it, but I think the Chair makes a very legitimate point.

There is certainly enough criticism going around as relates to our involvement in international organizations. There is a school of thought that feel we should not be involved in world organizations. They don't do much. There is too much waste, fraud and abuse, et cetera, et cetera.

Of course we all realize that much more good is done. There is always room for improvements, streamlining, getting a better job done, whether it is in our own agencies or even in our own individual personal congressional offices or whether it is in large corporations.

Boeing has problems from time-to-time, but they don't say, "Let's end Boeing." It might end itself.

So my point is that it hurts good things that are happening when you get either cynics—or it is truthful perhaps, I haven't seen the article—when you get criticism on a program like this, because then you have people saying, "Well you know what? We ought to just withdraw or let's not waste our money and let's just keep the money here."

I think that in—like I say, you are just there for a year. Listening to both of you, you certainly sound extremely interested, committed, able, but it is really important, I think more so than many people realize, in these times, that we ensure that we do the best job as possible to keep the critics, because there are some that simply say we should just withdraw from it all. Just forget it you know.

In order to prevent that kind of illogic from really getting a foothold and when they can point to something that is a legitimate flaw, like of course everyone else is flawless, but you found a flaw and they amplify it.

I would just like to associate myself with the Chairman's remarks about really giving all these things as serious a look as we can. Thank you.

Mr. SMITH. Thank you.

Would either of you like to add anything? I want to thank you very, very much. Yes?

Mr. MILLER. To echo that point with regards to both our bilateral programs and those that we pursued through membership organizations or multilaterally, they are critically important to each other and it was a high priority to have them implemented on the ground together most effectively.

Mr. SMITH. Thank you, and thank you very much for your great service and for being here today. I appreciate it.

Mr. MILLER. Thank you.

Mr. SMITH. I would like to now welcome our second panel to the witness table, beginning first with Youssou N'Dour.

The first ever Roll Back Malaria Concert took place in Senegal in March 2005. The event featured top African artists led by the internationally renowned Senegalese singer, songwriter and composer, Youssou N'Dour.

The event reached roughly 30,000 spectators and an additional audience of over 1 billion worldwide to celebrate Africa's creative energy and to bring a message of empowerment and hope to tackle its major scourge, malaria.

Roll Back Malaria partners, led by the U.N. Foundation, came together to raise funds needed to make the concert a reality.

We will also hear from Dr. Paul Nunn, who serves as Coordinator for TB–HIV and Drug Resistance in the Stop TB Department at the World Health Organization in Geneva. He leads a team of about 20 staff, which has responsibility for developing and implementing a global strategy for the reduction of the TB burden in high HIV prevalence settings and drug resistent TB strains.

Dr. Nunn has held a number of positions at the World Health Organization, including manager of TB–HIV issues, Stop TB Department and Secretary of the Global TB–HIV working group of the Stop TB Partnership.

From 1995 to 1998, Dr. Nunn served as the chief tuberculosis research surveillance unit in the global tuberculosis program, WHO, in Geneva.

Our first witness of the panel today will be Mr. Moeller, who is President and CEO of American Biotech Labs, a biomedical technology company. Previously Mr. Moeller was involved in the mining industry. He was Chairman of the Board of Clifton Mining, a position he has held for the last 8 years.

In addition, he was President of Contract and Mortgage Exchange. Before his involvement in the mining industry, he was a partner in Corporate Consultants, specializing in financial consulting and insurance underwriting.

Mr. Moeller, please begin the testimony.

STATEMENT OF MR. WILLIAM D. MOELLER, PRESIDENT AND CEO, AMERICAN BIOTECH LABORATORIES

Mr. MOELLER. Thank you, Mr. Chairman and Mr. Ranking Member and Members of the Committee. I am delighted to be here today.

I am William Moeller, Chairman and President of American Biotech Laboratories in Alpine, Utah. Our company produces engineered metallic silver, nano-sized particles in water-based products.

Our engineered silver has performed far beyond anyone's expectations as anti-microbial agent against a staggering variety of microbes, such as malaria, flesh-eating bacteria and E. coli.

ABL manufactures its water-based products by controlling and delivering a few thousand volts of A/C through highly purified sil-

ver electrodes. Sold in the United States, we began international distribution of our ASAP 10 product as a dietary supplement.

In the year 2001, a Rwandan medical facility called, seeking dosage instructions for a group of very young children who were in the last stages of malaria and were about to die.

I helped them understand the supplement dosages and days later, the Rwanda doctor contacted me again and told me that he had put ASAP 10 directly into bottles of 11 children who were about to die from malaria.

All 11 of the young children who had received ASAP got better during the next week. However, there were other children who had also been in the final stages of malaria and did not receive our ASAP 10. Sadly we found out that those other children had died, despite receiving the conventional treatments.

This affected me deeply and I realized that our ASAP 10 had some potent and positive affects on malaria patients. After we learned how the lives of the 11 children in Rwanda were saved, we initiated contact with four different hospitals in Ghana.

We shipped about a thousand bottles of our ASAP 10 to these different medical facilities. Obtaining good follow up clinical data turned out to be quite difficult, because once the patients felt better, they simply did not come back for further treatment and follow up.

However, word of the startling success of ASAP 10's affect against malaria gained such widespread acceptance in Ghana that the food and drug board of the Republic of Ghana issued a certificate of registration of a drug for the ABL product.

We have developed additional protocols for testing, which are in my written testimony. Some of the data show that out of 41 malaria patients, ages 1 to 90 years old involved in the studies and receiving ASAP 10, all 41 survived and there were no treatment failures.

All participating patients were deemed to have achieved full recovery on an average of 4 to 6 days. Clearly the data suggests that ABL's ASAP product, when administered in 2 to 3 teaspoon amounts 2 to 3 times a day, reversed the progression of malaria and saved lives.

The total cost of the regime for humanitarian use is only a few dollars and is highly effective. Further, no undesirable or drug-like side effects were reported by any of the patients in any of these more rigorous studies.

This result is also quite different from all other known malaria treatments, which often involve quite uncomfortable side effects.

ABL has sought the input of various malaria experts, including Dr. Marie Coll-Seck, Executive Secretary of the Roll Back Malaria Partnership, which is hosted by the World Health Organization.

Dr. Coll-Seck provided her comments, which resulted in a proposed 660-patient study, which is now being planned but not yet initiated.

Preliminary tests generated by two independent laboratories suggests the efficacy of ASAP 10 and ASAP–AGX–32 against TB. Because the data is new and not yet reviewed, we are reluctant to share any of this data at this time. However, we are encouraged by what we have seen.

ABL has invented and patented a process and a product that has the ability to kill a variety of bacterial, fungal and viral species. The production is robust and can quickly be scaled up to meet virtually any production demands.

The ASAP 10 product, in quantities of about an ounce per day, seems to eliminate malaria in human patients in 4 to 6 days. That is, an 8-ounce bottle of ASAP 10 has been more than enough to eliminate malaria in each of the patients involved in the African studies.

Mr. Chairman, ABL is ready to make this product available on a worldwide basis and we are seeking the Committee's assistance in guiding our efforts in obtaining global access to the humanitarian outlets. Thank you.

[The prepared statement of Mr. Moeller follows:]

PREPARED STATEMENT OF MR. WILLIAM D. MOELLER, PRESIDENT AND CEO, AMERICAN BIOTECH LABORATORIES

INTRODUCTION

Good Morning. I am William D. Moeller, Chairman and President of American Biotech Laboratories of Alpine, Utah ("ABL"), a company which produces engineered, metallic silver, nano-sized particles in water-based products. Our engineered silver particles have performed far beyond anyone's expectations as anti-microbial agents, against a staggering variety of microbes such as malaria, flesh-eating bacteria (MRSA—Methicillin Resistant *Staphylococcus aureus*) and *E.coli.*

Whether used on surfaces as disinfectants or if taken internally as supplements, all of our ABL products are non-toxic and have no known adverse human side effects. Our products have surprised many experts in the medical and science worlds because of their ability to combat bacteria, yeast, and viruses. ABL products have been proven to destroy anthrax spores and bubonic plague bacteria on surfaces, to eliminate the malaria parasite in humans and a host of other beneficial results.

We have developed five products to date as well as several other new products currently in our product development pipeline. We manufacture all of our products in the United States. One product ASAP–AGX–32 (a water solution containing 32 ppm of our engineered silver nano-particles) has already been approved by the EPA as a surface disinfectant for hard, non-porous surfaces in commercial, residential, industrial, hospital and medical environments. Another product called Silgel is a non-toxic moisturizing gel, which utilizes our ASAP–AGX–32 as a raw material supply of silver particles. It is currently undergoing the final steps for FDA approval for the treatment of lacerations, first and second degree burns, abrasions, surgical wounds, skin ulcers etc. Several other new ABL products will soon warrant the filing of new FDA and/or USDA applications.

BACKGROUND

All my life I have been involved with the mining and processing of silver in Utah. I am Chairman of the Board of Clifton Mining, a Utah mining company holding several million ounces of silver reserves. My family and I are large stockholders in Clifton Mining. I have spent most of my life in Utah where my wife Jeneane and I raised our seven children together.

In the late 1990s, the price of silver reached a point where its mining and production costs were above its selling price. At that time, we needed to find an alternative use for silver that at least paid for removing the silver from the rock ore. We decided to devote some the resources of Clifton mining to try to create a new water-based product containing silver. Since ancient times it has been known that silver inherently possesses desirable antimicrobial and immune boosting properties. We planned to be the first to maximize those desirable effects of silver. We did our homework and found a plethora of colloidal silver products and devices littering the marketplace, most of which did not seem very sophisticated to us. Our analyses of various colloidal silver products (mainly dietary supplements) led us to the conclusion that these manufacturers lacked stature in the marketplace and the products produced were, at best, anecdotally effective.

In 1998 we created ABL with the idea of manufacturing high quality, standardized colloidal silver products. I talked all five of my sons into joining ABL in what we thought might be a nice family business. We worked hard inventing new meth-

ods to purify and standardize our silver products and, frankly, got a little lucky along the way because we ended up inventing and manufacturing something else all altogether.

Our initial discoveries are the subject of two issued US Patents: 6,214,299, which issued on April 10, 2001 and related US Patent 6,743,348, which issued on June 1, 2004 (See Appendix 1). Additional discoveries are contained in several other pending patent applications, most of which are not yet in the public domain.

Although ABL's initial products were referred to as "colloidal silver," we now know that our engineered particles are quite different. When most people use the phrase "colloidal silver," they mean ionic silver, silver salts or silver nitrate in a gelatin matrix. ABL's liquid products do not contain ionic silver, silver salts or silver nitrates. Rather, they contain engineered nano-sized particles of metallic silver dispersed in a matrix of pure water. Although these products are primarily water (99.999%) because the actual silver concentration is so low. Their unique potency has been demonstrated by numerous laboratory (in vitro) and human (in vivo) tests carried out by ABL, at ABL's request, and in some of the most interesting cases, without ABL's involvement or even contemporaneous knowledge.

ABL's first three products that we manufactured were dietary supplements. These products have actual silver concentrations of 10 parts per million ("ppm"), 14 ppm and 22 ppm and are sold through a number of different outlets. For example, ASAP 10 (the 10 ppm product) is being sold through General Nutrition Center stores throughout the country under the name *Silver Biotics*. This 10 ppm of silver particles in purified water is colorless, tasteless, odorless and is non-toxic. Based on our knowledge of the engineering of the metallic silver particles, we estimate the actual shelf life of our products to be in excess of 10 years.

As demand for our products grew, we began distributing ASAP 10 worldwide. In short order, many different positive antidotal stories began to pour in from around the world. The interest in our product grows and certain private investors joined our core "family and friends" group. One user's experience led to an important event that would forever open our eyes to the power of our 10 ppm ASAP non-toxic liquid.

In 2001, twelve bottles of our 10 ppm ASAP product fell into the hands of a medical Doctor in Rwanda, Dr. Ewabuhihl Ezechias. One day I received a frantic telephone call from Dr. Ezechias' office that was in Rwanda caring for a group of very young children who were in the last stages of malaria about to die. Dr. Ezechias was looking for instructions on how to administer our ASAP 10 product to these desperately ill children. I suggested to the Doctor that he measure out a teaspoon or two to each of the children, two or three times a day and that he repeat the process until the children hopefully showed some improvement. He responded abruptly that there was no time for measuring anything—the situation was far too grave for "such niceties." All of these children had temperatures around 105 degrees, had not improved with conventional treatments and were all about to die. He asked me if he could simply put the water into their bottles. Knowing of its totally non-toxic properties and sensing his desperation, I assured him that it would not hurt the children.

Days later, Dr. Ezechias contacted and told me that he had put the ASAP 10 ppm water directly into the drinking water bottles of 11 of these children. All 11 of the young children who received the ASAP 10 ppm got better. A week later, the 11 left his clinic alive and healthy. Sadly, there were other children who did not receive the ASAP treatment. Those children died in spite of receiving all the conventional treatments which Dr. Ezechias provided them. This affected me deeply and I realized that our ASAP 10 ppm had potent, positive effects on malaria patients. Besides the phone calls, we also received an indirect written communication from Rwanda which is included in Appendix 2.

Word spread quickly and soon scientists and medical doctors from around the world began to hear stories about ABL's silver products. One doctor from Mumbai, India, Dr. Dilip Mehta of Viridis BioPharma decided to check out the many stories. Without our knowledge, he began to test our products in a variety of different ways against several different micro-organisms. Dr. Mehta scientifically tested and compared our products with other silver-based products from around the world. Dr. Mehta concluded that no other product in the world had the biological efficacy of our non-toxic ASAP 10 ppm product. Traveling half-way around the world from India to Utah, Dr. Mehta unexpectedly showed up at our Alpine facility to begin a trusted and fruitful association advancing our knowledge and product base.

We also have met many important scientists along our journey, including Professor Rustum Roy who concurrently holds appointments with Pennsylvania State University, Arizona State University, and the University of Arizona. Professor Roy is a world leading materials scientist (please refer to *www.rustumroy.com*) whose initial interest was in determining and characterizing the physical properties of our

water products. Because he was interested in water and its relationship to general health, Professor Roy wanted to correlate physical properties of ABL's water-based silver products with their superior biological performance. He found that our ASAP 10 and ASAP–AGX–32 water-based products are physically quite different in a number of inherent, measurable, physical properties from colloidal silver products. Professor Roy has now generated much data showing that our products are unique. Professor Roy has presented this data at several scientific conferences. Please see Professor Roy's letter in Appendix 3.

Professor Roy, in turn, introduced us to General Resonance, a cutting-edge science and technology company located in Maryland, whose work and expertise Professor Roy had scrutinized and tested at the Materials Research Laboratory at Penn State. ABL and General Resonance recognized their potential synergy and have formed a joint venture. The combination of General Resonance's fundamental understandings and its patented sciences and technologies with ABL's existing products and technologies promises to generate a long-lasting pipeline of new, more potent products with a broader use spectrum (or even targeted specifically to particular diseases). Other joint ventures are likely. Clearly there has been much interest generated in ABL's new non-toxic products.

THE TECHNOLOGY

ABL manufactures its water-based products by controlling and delivering a few thousand Volts AC through highly purified silver electrodes in contact with the surface of high purity water. The silver in the electrodes is slowly dispersed into the water as metallic silver nano-sized particles. These engineered silver particles currently vary in size between about 10–50 nanometers in diameter, depending on the particular manufacturing conditions. Concentrations as low as 1–2 ppm have been shown to have efficacy against certain bacteria and viruses, however, the products being sold right now typically range in concentration of from 10 ppm—32 ppm (i.e. ASAP 10 and AGX 32, both of which are greater than 99.999% pure water). These concentrations have been shown to kill or de-activate bacteria and viruses in a few minutes. Appendix 4 shows in brief summary form certain in vitro results and data which demonstrate the broad spectrum efficacy of ABL silver-water solutions against a variety of microbes (and related human diseases).

The data in Appendix 4 (along with other data not presented today) suggest that small amounts of selectively engineered silver particles can have dramatic anti-bacterial, anti-fungal, and anti-viral effects. Surface disinfectants (e.g., bleach) and most pharmaceutical products against these agents of disease function by various chemical reactions and are consumed and used up in the process. These agents that are consumed in this way must be replenished to remain effective. Our silver particles function differently and it is clear from ongoing research that our engineered silver particles are not consumed in chemical reactions the way other anti-microbial agents are. Rather, it appears that the silver particles function as catalysts, which promote certain lethal reactions in only unfriendly microbes (i.e., the destruction of bacteria, fungi and viruses). This is the same way platinum particles in an automobile's catalytic converter function. They promote lethal reactions in pollutants without being consumed in the process. We believe that this understanding is very important and partly explains the lack of any known negative biological side effects from the ABL products. If engineered properly, very small amounts of catalytic silver apparently can go a very long way.

MALARIA STUDIES

After ABL learned how the lives of the 11 young children in Rwanda were saved (discussed above) ABL initiated contact with four different hospitals/clinics in Ghana. We shipped to these different medical facilities about 1000 of our 8 ounce bottles of ASAP 10. Obtaining good follow-up clinical data turned out to be quite difficult because once the patients felt better; they simply did not come back for further treatment and follow-up. For example, Appendix 5 contains representative data from the Justub Clinic, run by Dr. Agnes Abraham, who reported after her first trials, that typically their patients return to the clinic only if they are still ill, which was not the case with their patients treated with the ASAP 10.

Another preliminary trial occurred at the Air Force Hospital in Ghana where the Medical Officer in Charge was Dr. Evelyn Kwabiah. The five patients treated by Dr. Kwabiah all had positive outcomes (see Appendix 6). Dr. Kwabiah reported that patients with malaria who had received the ASAP 10: recovered faster than those receiving conventional treatments; recovered where conventional treatments had failed; or, that the ASAP 10 functioned as a prophylactic preventing the recurrence of malaria.

Ultimately, the success of ABL's ASAP 10 ppm against malaria gained such widespread acceptance in Ghana that the Food and Drugs Board of the Republic of Ghana issued a Certificate of Registration of a Drug for ABL's product (see Appendix 7).

Although we were receiving better clinical reporting, and Ghana had issued a Certificate of Registration, we still were not satisfied that the previous trials met the level of standardization we wanted to achieve. To obtain better data concerning ASAP 10's effectiveness against malaria, ABL (in cooperation with competent university medical professionals) designed a new protocol (see Appendix 8). The new protocol required that all Malaria patients be monitored for 15 days and were encouraged to return for follow-up testing and assessment with financial incentives (patients were paid a few dollars a day to come back and be monitored and tested). Appendix 8 contains the study protocol, results, and one representative patient's chart. (An Executive Summary of these more reliably executed Malaria Studies in Ghana, supported by ABL, is shown in Appendix 9).

Study #3 listed in Appendix 9 was the most reliable of the studies and used the protocol described in Appendix 8. The data showed that out of the 41 Malaria patients (ages 1–90 years) involved in the studies and receiving ASAP 10, all 41 people survived and there were no treatment failures. All participating patients were deemed to have achieved full recovery in an average of 4.5 to 6.5 days, with recovery time differences probably being due in part to differences in total dosages. Clearly the data suggest that ABL's ASAP 10 ppm product, when administered in 2–3 teaspoon quantities 2–3 times per day (i.e., one ounce per day) reverses malaria and saves lives. The cost of this regimen in total is a few dollars and appears to be highly effective.

No undesirable or drug-like side effects were reported by any of the patients in any of these more rigorous studies. We believe that this was because the ASAP 10 ppm is primarily water with very small amounts of catalyst-like metallic silver particles therein,. This result is also quite different from all other known malaria treatments, which often involve quite uncomfortable side effects.

ABL has continued its efforts to determine the effectiveness of its ASAP 10 ppm product as an effective treatment against malaria. To that end, ABL sought the input of various malaria experts including that of Dr. Awa Marie Coll-Seck, Executive Secretary of the *Roll Back Malaria Partnership* hosted by the World Health Organization. Dr. Coll-Seck provided her comments which were instrumental in creating a proposed 660 patient study; initially to be performed in Senegal. This Protocol was just completed earlier this month, but has not yet been initiated. ABL hopes to be able to accomplish this or a similar study in the near future so that we can begin to have a larger impact on malaria worldwide.

TUBERCULOSIS

Preliminary data generated by two independent laboratories suggest an efficacy of ASAP 10 ppm and ASAP–AGX–32 against tuberculosis. But, because this data is new and not yet reviewed, we are reluctant to share any of the data at this time. However, we are encouraged by what we have seen.

OTHER PRODUCTS OF INTEREST

1. Surface Disinfectant.

ABL received EPA approval for ASAP–AGX–32 in 2003 (see Appendix 10). ABL also received a contract (Contract No. V797P–5762X) with the VA Hospitals, to use this product as a surface disinfectant. Appendix 11 shows data recently generated by an independent laboratory comparing AGX–32 to eight leading disinfectants for use against Methicillin resistant *Staphylococcus aureus* (MRSA). The data is reported two different ways: (1). "*% Effectiveness*," which compares how effective the leading disinfectant is compared to AGX–32 (e.g., "Phenol" is 40% as effective as AGX–32); and (2) "*Coefficient*," which shows the reverse or how much better AGX–32 is relative to the leading disinfectant (e.g., AGX–32 is 2.5 times more effective than Phenol). These data are very significant because AGX–32 is a non-toxic product, unlike most disinfectants, and yet functions as well or better than the other disinfectants. It can be used around hospitalized patients without any ill effects. Moreover, because the silver functions akin to a catalyst, it is not consumed in a chemical process and will continue to disinfect a surface until removed (e.g., by soap and water) from the surface on which it was applied.

2. Wound Care and Burn Care.

ABL has a 510(k) application pending with the FDA (see Appendix 12) for AGX SILGEL, a moisturizing gel containing ABL engineered silver particles. ABL expects

the final animal study required for this FDA approval for wound care to be finished in June 2005. We anticipate that approval will be obtained for use of the SILGEL silver-gel product on: lacerations, abrasions, skin tears, leg and other surface ulcers, surgical wounds, first and second degree burns etc. The base material for manufacturing this product is ASAP–AGX–32 (a non-toxic precursor). This AGX SILGEL product is a broad spectrum, anti-microbial. SILGEL is not cytotoxic in studies performed to date (e.g., the gel has been proven to be non-toxic in the oral route, by mouse model studies up to 5000mg/kg of body weight). ABL's silver-gel provides moisture for wound healing and burn treatment, has no color or smell, requires no refrigeration and remains stable from 17–113 degrees Fahrenheit. In FDA approval comparison studies, AGX SILGEL was found to be over 10 times more effective in killing MRSA compared to a leading FDA approved silver-based product (at a challenge of about 10,000,000 bacteria/ml), even though the leading and approved product contains more than 300 times as much silver than AGX SILGEL.[1]

Dr. John A. Shaw, a practicing oncologist in Arizona, has recently been using AGX Silgel on an experimental basis to treat radiation burns from radiation therapy used for treating breast cancer. His reviewed work has been conducted at hospitals in Arizona. His initial findings are that the AGX Silgel promotes healing more effectively than other commercially available products. A letter from Dr. Shaw is included in Appendix 13.

GOVERNMENT ACTIVITIES OF INTEREST

ABL has initiated a number of recent US Government contacts, which have resulted in the testing of ASAP–AGX–32 and AGX Silgel products (or at least the desire to test). Many of these contacts have generated desirable data showing the efficacy of ABL's products for different uses. We have not offered these products for sale to the government yet.

Letters of support for ABL from Senator Orrin Hatch and Lt. General Paul K Carlton, Jr., addressed to The Honorable Tom Ridge, can be found in Appendix 14.

CONCLUDING STATEMENT

ABL has invented and patented a process and a product that should have wide applicability to a variety of bacterial, fungal and viral species. The production process is robust and can be quickly scaled-up to meet virtually any production demands. The ASAP 10 ppm product, in quantities of about 1 ounce per day, seems to eliminate the symptoms of malaria in human patients in about 4–6 days. Thus, one 8 ounce bottle of ABL's ASAP 10 ppm has been more than enough to eliminate the symptoms of malaria in each of the patients involved in the African studies. ABL is ready to make this product (or the process) available on a world-wide basis. We hope that the Committee will be sufficiently impressed to help us to help others.

Mr. SMITH. Thank you very much, Mr. Moeller.

Mr. N'dour.

STATEMENT OF MR. YOUSSOU N'DOUR, SENEGALESE JAZZ MUSICIAN, SPECIAL ENVOY, ROLL BACK MALARIA PARTNERSHIP AND UNICEF GOODWILL AMBASSADOR

Mr. N'DOUR. Thank you, Chairman Smith, Congressman Payne, other witnesses today. Every day 3,000 people die in Africa. Every year more than 2 million people die because of malaria. Most of the people are children and pregnant women.

I want to really say like every way people have a right to live in Africa also. Before, when you talk about malaria to people, you know like call someone have appointment like tomorrow, he said, no. Okay, see you tomorrow maybe because my kids are getting little malaria. He didn't realize how dangerous the malaria is and the next night, maybe he is going to have the bad news.

What we did now I think make things happening is people understood the danger of malaria now in Africa and we are doing a lot of things, more things like sports people, musicians, politicians.

[1] This product has not been offered for sale due to the pending FDA Application.

Last month we did what we call Africa life in Senegal, in Dakar, where there was more than 20,000 people every day and through the communication of the artists, biggest name, African name, getting the message and delivering the message to the local people, and now people know exactly the danger of malaria.

I think what we need to stop malaria is bed nets, ACT medicine, and a way also to stop the mosquitoes. I think people already know the danger.

I hear also from the many African leaders; political leaders, mobilizing, sharing the mobilization to focus on malaria. Why?

They know this keeps our economy down in Africa. Sick with malaria, you can't go to work. Children can't go to school.

I know, Mr. Chairman, the United States already give a lot, but we need more. More bed nets. More medicine. More support for local communication. If America is leading the way to fight malaria, the European Union and the rest of the world will follow.

The Global Fund and Roll Back Malaria need your support. This is why I am here to represent all the voice of Africa and people who live the reality and the affect of the malaria, and we definitely need your support.

Malaria is not about numbers. It is about family. During the Africa life I mentioned before last month we lost one of the best dancers in Africa, Mr. Consel, because of malaria.

Last thing. I really feel the world changing from me. If you heard about greot, greot are the storytellers in Africa. Before we have radio or TV, people were giving all the information to the greot to deliver to the people and I feel the world changing to have a chance to talk to the Congress, show how much the world is changing.

Thank you for your support, your leadership, and to invite me to speak about malaria. Thank you so much.

[The prepared statement of Mr. N'Dour follows:]

PREPARED STATEMENT OF MR. YOUSSOU N'DOUR, SENEGALESE JAZZ MUSICIAN, SPECIAL ENVOY, ROLL BACK MALARIA PARTNERSHIP AND UNICEF GOODWILL AMBASSADOR

Chairman Smith, Congressman Payne, thank you for inviting me to testify on behalf of the Roll Back Malaria partnership and the hundreds of millions of people around the world who are threatened each day by the scourge of malaria. I commend this committee and the U.S. Congress for its strong leadership in the fight against malaria and other global pandemics such as tuberculosis and AIDS.

I would also like to take a moment to express my gratitude to Dr. Dybul and the other esteemed witnesses at this hearing for their important efforts in this fight. Millions of lives will be saved in Africa and around the world thanks to their work and that of their colleagues both here in Washington and in affected countries.

The Intolerable Toll on Africa

I speak before you today as not only a representative of the Roll Back Malaria Partnership and UNICEF, but also as an African citizen who has witnessed and endured the devastating impact of the malaria. I come from Senegal, a small West African country of 10 million people roughly the size of the state of South Dakota. Each year, more than one million people in Senegal experience the shaking chills, fevers and sweats of malaria.[1] Some are incapacitated for days or weeks, losing valuable time at work or school. Others, mostly children under the age of five, are not so fortunate. Thousands of Senegalese children die of malaria and its effects each year. The children that do survive a bout of malaria are often left with anemia, neurological damage, or other disorders which threaten their health and development.

[1] World Health Oranization/UNICEF, *The Afria Malaria Report 2003*,(WHO/UNICEF, 2003, Geneva)

Sadly, Senegal's story is not unique. Countries throughout sub-Saharan Africa bear a similar, and often greater, burden of malaria. Nearly one million Africans die from and more than 300 million are debilitated by malaria each year.[2] Hospitals and clinics throughout the continent are flooded by people seeking treatment and care for severe malaria episodes. In some areas, half of all hospital admissions are due to malaria alone. The disease is not only taking a terrible human toll, but is also crippling the economic potential of the continent. Factories and farms operate below capacity because workers are frequently incapacitated by malarial illness. Classrooms are filled with the empty chairs of children who lie at home shaking and sweating. Economists conservatively estimate that malaria costs Africa $12 billion—1.3 percent of its aggregate gross domestic product—in lost productivity each year.[3]

An Effective Arsenal

For decades, we had a simple weapon we could use to fight back against this killer, a drug called chloroquine. It was cheap, safe, and effective, curing a child in three days for just ten cents, and countless lives were saved. However, the medicine never reached everyone who needed it. On average, less than half of infected African children received any form of treatment.[4] But recently, those who have taken chloroquine have found that it has had little or no effect. The deadliest malaria parasite, *plasmodium falciparum*, has adapted to resist the effects of chloroquine and other effective drugs. Over time, these drug-resistant parasites have spread so widely that today, a standard treatment will fail to cure 80 percent of malaria cases in some areas. Infection and death rates around the world have risen dramatically as a result.

Despite the loss of chloroquine, effective tools exist to prevent and treat malaria and more are on the horizon. All of these tools have two traits in common: they are cheap and they are effective.

The solution to the rise of drug-resistant malaria parasites is artemisinin-based combination therapies (ACTs), a group of medications formed from a Chinese plant which has been used to treat malaria fevers for centuries. These medications are not only highly effective, curing 98 percent of cases in three days, but they also prevent the development of drug-resistance by attacking the parasites from multiple directions. Unfortunately, though inexpensive by American standards, the $1.50 average cost of these medications is more than the daily income of most African families. As a result, many African countries were slow to change their treatment programs from the much cheaper chloroquine. However, in the last year, the Global Fund to Fight AIDS, Tuberculosis and Malaria has devoted new resources to underwrite these treatments, facilitating a massive shift to ACTs across Africa.

While treatment is essential, our first line of defense against malaria must be to prevent new infections by driving back its mode of transportation, *Anopheles* mosquitoes. There are several potent insecticides which can deter and destroy these tiny killers while causing no harm to humans. There are two principle methods of putting these insecticides into action: infusing them into the fibers of mosquito bed nets or spraying them on the walls of homes.

Bed nets have been available as malaria protection for centuries, but a recent innovation has greatly improved their effectiveness. Scientists have devised a way to integrate the insecticide into the synthetic fibers of the net so that it is released slowly over time. These new, long-lasting insecticide-treated bed nets (LLITNs, in the parlance of our times)cost just $5 and retain their full protective power for more than five years. When enough of these nets are deployed in a village, the mosquito population is decimated, and even those children who do not sleep under nets benefit from them. Scientific studies have found that when these nets are used by the majority of homes, mortality in children under the age of five from all causes—not just malaria—is reduced by roughly 20 percent.[5] Since malaria is only one of a number of major killers of young African children, this means nets can reduce child malaria deaths by as much 80 percent.

For decades, indoor residual spraying (IRS) with DDT was our primary weapon against mosquitoes. While there are now others, DDT remains the most effective op-

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[2] Ibid.

[3] Gallup, John Luke and Sachs, Jeffrey D. "The Economic Burden of Malaria." The American Journal of Tropical Medicine and Hygiene, vol. 64, no. 1, 2, S (January–February 2001) pp. 85–96

[4] World Health Oranization/UNICEF, *The Afria Malaria Report 2003*,(WHO/UNICEF, 2003, Geneva)

[5] Lengeler Christian, Sharp Brian (2003) "Indoor residual spraying and insecticide-treated nets." In: *Reducing malaria's burden: evidence of effectiveness for decision makers,* (Global Health Council, 2003, Washington, D.C.). pp. 17–24. http://www.globalhealth.org/assets/publications/malaria.pdf

tion we have in some situations and we must continue to use it. Spraying programs are sometimes dismissed as inefficient and costly because of the labor-intensive systems that are needed to roll them out. But programs in Mozambique, South Africa, and Zambia, among others, have drastically reduced malaria infections with relatively little cost, particularly in urban areas. In fact, studies have shown that IRS and LLITN programs are roughly equivalent in cost-effectiveness.[6]

All of these tools have a critical role to play in our efforts to control malaria, but this is not always acknowledged. Yesterday, I joined people across the world in recognizing Africa Malaria Day under the theme of "Unite Against Malaria." Even those of us who care passionately about the fight against malaria must work hard to achieve that simple goal. We must agree that LLITNs and IRS each have their place in our arsenal, chosen case by case, based on local conditions and the preferences of the country. We must agree that sometimes a bed must be provided for free and sometimes it must be sold for a small cost. And yes, we must agree that DDT is still needed to save thousands of lives.

By effectively implementing these tools, we can rapidly and dramatically drive down malaria infection rates across wide areas. A Global Fund-supported program in Lubombo Region of South Africa, Mozambique and Swaziland has reduced malaria prevalence by 90 percent through comprehensive insecticide spraying and delivery of ACT treatments.[7] Success stories such as these have led Professor Jeffrey Sachs and others to refer to malaria as the "quick win" in war against global poverty. It is not fantasy for us to imagine meeting the Millennium Development Goal of significantly reducing the global incidence of malaria by 2015.

New Hope on the Horizon

While the tools to eradicate malaria exist, the scientific community is working to create new ones. In the past three years, the Bill and Melinda Gates Foundation has channeled unprecedented resources into research for effective new malaria treatments and vaccines. The Medicines for Malaria Venture, a non-profit research foundation, has made great progress in synthesizing artemisinin, the key component of the highly effective ACT medications, which would dramatically cut the cost of these critical treatments. Last year, a successful trial by the Malaria Vaccine Initiative generated hope that an effective vaccine might be available in the next five years. It would not be a panacea, but even a partially-effective vaccine could save millions of lives.

As we work to scale-up the tools we already have, we must ensure that these important research efforts are not neglected. Even with the tremendous generosity of the Gates Foundation, more resources are needed to realize the full potential of these projects. I urge the world community, including the U.S. government, to support these needs.

Critical Engines

These tools are only truly useful to us if we can deliver them to the people who need them most: tens of millions of the poorest and most vulnerable people living in the rural areas of Africa. It is a daunting task and there are many challenges—from the exodus of skilled health professionals, to weak national health budgets, to counter-productive taxes and tariffs on bed nets and others interventions. But these challenges have been overcome many times before. A recently published book by the Center for Global Development, *Millions Saved: Proven Successes in Global Health*, describes large-scale programs which successfully defeated diseases such as smallpox and river blindness in the face of similar obstacles.[8]

A host of partners, from small faith-based groups to bilateral development agencies, are working tirelessly to implement malaria control on a wide-scale in Africa. I wish to focus my remarks on two of these critical mechanisms, which have driven substantial new progress in the fight over the past three years: the Global Fund and the Roll Back Malaria Partnership.

The Global Fund to Fight AIDS, Tuberculosis and Malaria

The Global Fund to Fight AIDS, Tuberculosis, and Malaria, is a global partnership created three years ago to effectively raise and allocate massive new resources

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[6] Lengeler Christian, Sharp Brian (2003) "Indoor residual spraying and insecticide-treated nets." In: *Reducing malaria's burden: evidence of effectiveness for decision makers*, (Global Health Council, 2003, Washington, D.C.). pp. 17–24. http://www.globalhealth.org/assets/publications/malaria.pdf

[7] "Lubombo Region: Rolling Back Malaria in Southern Africa" (Friends of the Global Fight Against AIDS, Tuberculosis and Malaria, 2005, Washington, D.C.)

[8] Levine, Ruth *Millions Saved: Proven Successes in Global Health Center for Global Development, Washington, D.C; November, 2004.*

to fight these diseases. To date, it has committed more than $3.2 billion over two years to effective programs in 127 countries around the world. It has quickly become the largest single financier of malaria control, allocating nearly $1 billion over two years to 70 countries. The Global Fund's approach has ensured that its resources are helping all those who are engaged in the fight at the local level, including non-governmental and faith-based organizations, the private sector as well as national governments. Half of its resources are committed to non-governmental entities.

The Global Fund is the primary mechanism for U.S. efforts to fight malaria and tuberculosis worldwide. In FY2005, 61 percent of U.S. funding to fight malaria and 42 percent of funding to fight tuberculosis was channeled through the Global Fund.[9] The U.S. is the Fund's largest single donor, contributing more than $1 billion to the Fund to date. Roughly $450 million of this amount is being used to fight malaria and TB. The Global Fund also works closely with Ambassador Tobias to coordinate efforts to fight the AIDS pandemic.

Global Fund resources have already had a significant impact. By the end of 2004, its malaria programs had distributed nearly 1.4 million ITNS and provided 300,000 ACT treatments. Its results on TB and AIDS were similarly robust, with nearly 400,000 people treated for TB and 130,000 people receiving life-prolonging AIDS treatment. And its portfolio is still young. Within the next five years, its current malaria programs plan to distribute 108 million bed nets and more than 145 million ACT treatments.

The Global Fund's impact can already be seen at the country level. In the Lubombo Region of Southern Africa, it has built upon a successful program launched by a group of more than 100 private companies, which recognized the economic benefits of controlling malaria in the area. Global Fund resources have enabled the program, which has reduced malaria prevalence by 90 percent across large areas of the region, to expand its activities to more than 40,000 square miles. In Zambia, the Churches Health Association of Zambia has used Global Fund money to purchase and distribute nearly 35,000 ACTs and 18,000 bed nets through more than 250 local faith-based organizations.[10]

This morning, I joined leaders from the U.S. Congress and international organizations to announce one of the Global Fund's latest accomplishments. Last spring, the Global Fund responded to critiques from the academic community and U.S. Congress that it was funding outdated and ineffective malaria treatments such as chloroquine by undertaking a massive review and reprogramming of its malaria treatment grants. With the help of the Roll Back Malaria Partnership and other partners, the Global Fund switched its grants in 19 countries to the more effective ACTs. This process has begun to show success. The Global Fund will sign grants that will enable seven African countries to purchase more than 100 million ACT treatments over the next two years. Other grants in its malaria portfolio will purchase at least 100 million more. This is one of the most rapid expansions of a drug treatment in the history of global public heath—only 10,000 ACTs were used in sub-Saharan Africa two years ago.

The Roll Back Malaria Partnership

The Global Fund is the war chest in the fight against malaria, providing much of the financing needed to scale-up control programs. But it cannot win this fight alone. Countries need help in choosing which tools to use and ensuring they are purchased and distributed swiftly and effectively. This is the function of the Roll Back Malaria Partnership (RBM). Established in 1998, RBM brings together major partners, including donor and endemic country governments, multilateral agencies, private corporations and foundations, NGOs, and academic institutions, to steer the fight against malaria through increased coordination and key policy decisions. At its founding, the partnership set the goal of halving the burden of malaria worldwide by 2010.

RBM has a corps of key staff who help enact the policies and implement the goals of the Parnership's Board. Under the strong leadership of Dr. Awa Marie Coll-Seck, the RBM Secretariat has played an important role in ensuring countries have access to the tools they need. Last year, it facilitated the transfer of LLITN technology from the Sumitomo Chemical Company in Japan to the AtoZ Corporation in Tanzania. This has significantly increased the global production of LLITNS and dramatically reduced the shipping costs to African countries. Together with the Global Fund and other partners, RBM also helped 19 countries switch their national treatment policies to ACTs.

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[9] Foreign Operations, Export Financing, and Related Programs Appropriations Act, 2005

[10] "The Churches Health Association of Zambia" (Friends of the Global Fight Against AIDS, Tuberculosis and Malaria, 2005, Wahington D.C. www.theglobalfight.org)

RBM Secretariat staff has also helped countries clear obstacles that have hindered the implementation of large-scale malaria control programs. In Tanzania, for example, an ambitious, Global Fund-sponsored plan to distribute bed nets through a voucher scheme linked to antenatal clinics was faltering because of inefficient structures. RBM convened experts to help the CCM revise the work plan and accelerate scale-up of the program. As a result, nearly half of the country now has access to the voucher scheme. In Malawi, RBM brought together the major local and international partners to reach consensus on the best strategies for distributing bed nets. This has contributed to a growth in national ITN coverage from 12 percent to 58 percent in just two years. In these and other countries, RBM is ensuring that U.S. taxpayer money, through the Global Fund and other mechanisms, is having the maximum impact on the lives of people affected by malaria.

More Resources Now Needed to Achieve "Quick Wins"

The Global Fund and RBM Secretariat need more resources to sustain and expand their important work.

With the help of U.S. financial support, the Global Fund has launched more than 300 programs, which have already impacted the lives of millions of people threatened by malaria, tuberculosis and AIDS. Many of these programs are approaching the end of their initial two-year grants and require additional funding to continue their work for the full five-year program term.

In 2006, the Global Fund requires $2.4 billion just to renew these existing successful grants. In addition, the Global Fund's Board has also launched a new round of grants to ensure that its efforts keep pace with the constantly growing devastation of the three diseases. It estimates that it will need $1 billion to approve a robust round of new grants.

I urge the Congress to meet one-third of this total need, *$1.1 billion*, in the FY2006 budget process to ensure that the Global Fund is not forced to terminate effective life-saving programs

The RBM Partnership Secretariat urgently needs additional resources. This year, it requires $3.6 million just to continue its operations at the current level and more than $15 million to fulfill the objectives identified by the partners on its Board. The U.S. has already contributed $700,000 this year through the US Agency for International Development, but more is desperately required.

I urge the Congress to contribute at least *$1.2 million* more (one-third of the immediate shortfall) and to call upon another other donor country governments in Europe and around the world to match that commitment.

Mr. SMITH. Mr. N'Dour, thank you so much for being here, and for the goodwill you promote and the focus you bring by traveling all around the world, but especially in Africa on this very important subject. Thank you so much for being here and honoring us with your presence.

Dr. Nunn.

STATEMENT OF PAUL NUNN, M.D., COORDINATOR FOR TB/HIV AND DRUG RESISTANCE, STOP TB DEPARTMENT, WORLD HEALTH ORGANIZATION

Dr. NUNN. Chairman Smith, Mr. Payne, Members of the Subcommittee, on behalf of the World Health Organization, I thank you for the opportunity to brief you and the Committee today.

In the interest of time, I will not read out the entire written testimony, but will just focus on some salient points.

I think the first thing to say is that the TB community has developed and promoted an effective TB treatment strategy, DOTS, which you have described well. It has developed a single global plan, a single global monitoring and evaluation system, that reports each year, through WHO, and a single coordinated partnership.

This partnership is housed in WHO, involves now more than 300 partners and the U.S. Government has made a major contribution to this partnership, especially through the highly valued work of

the Centers for Disease Control and Prevention and the U.S. Agency for International Development, and WHO thanks the U.S. Government for that contribution.

About 9 million people around the world fall sick with tuberculosis every year, and each year 2 million lives are claimed by the disease.

As we have already heard, the good news is that TB is treatable and the drugs cost a little more than $10. Between 1995 and 2003, 17 million TB patients have been treated under the DOTS strategy, with full engagement and commitment of ministries of health.

China and India particularly have shown how to accelerate distribution of DOTS and have rapidly scaled up and in 2003 notified 1.7 million cases between them.

As a result of all these and other efforts, in five out of six continents the number of TB cases, new TB cases, is either falling or stable and the Millennium Development Goals are therefore likely to be met.

Unfortunately, Africa is the one continent where TB rates are rising sufficiently to cause an increase in global rates.

We estimate that 2.3 million cases of TB occur annually in Africa, which reports some 24 percent of the total notifications worldwide and yet the region holds only 11 percent of the world's population.

HIV is the biggest single challenge to TB control efforts on the continent. The cause is quite simple: As HIV rises, so TB rises and at the same time, tuberculosis accelerates the progression of HIV to AIDS.

In 2003, over 80 percent of the global total of deaths among TB–HIV co-infected patients were in Africa and this is over 200,000 individuals.

The life expectancy of an HIV-infected person with TB is measured in weeks if treatment is not available and unfortunately, future projections for HIV are not optimistic. UNAIDS estimates that a fall in the numbers of HIV-infected people in Africa, before 2010, is unlikely.

In Bangkok, in 2004, Mr. Nelson Mandela said to fight against AIDS, we must do more to fight tuberculosis, but so far this advice has gone largely unheeded.

Over half a million HIV-infected people develop TB annually in Africa. These individuals are eligible for anti-retroviral treatment and nearly 300,000 each year are already in contact with the health service. Thus TB programs are important entry points for ART scale up, as well as a potential significant assistance toward reaching the goals of the U.S. President's Emergency Plan for AIDS relief, notably those of treating 2 million HIV-infected people with anti-retroviral drugs.

But HIV isn't the only problem. Poverty, the weak infrastructures and health systems that are the consequences of poverty are also a problem in Africa. Even existing health systems and services are weak and sometimes poorly organized.

The lack of sufficiently trained staff is consistently cited as the main constraint facing TB control. In sub-Saharan Africa, there is only about one health worker per 1,000 population.

Despite considerable increases in the funding available for TB control from governments of the high TB incidence countries and from donor countries, almost all African countries face a shortfall in the funding needed to reach the global targets.

Statements of political commitment by government leaders must be matched by concrete support, in terms of increased funding. The Global Fund has been mentioned already and is clearly a significant and innovative forward step and I am sure will make a large contribution toward TB control, if it can ensure rapid movement of the funding to where it can be used.

So what then needs to be done? Well firstly, unprecedented, coordinated efforts are needed by government, donors, technical agencies and all the other players in Africa, in close collaboration with national TB and AIDS control programs and with the emerging Pan-African institutions, such as the African Union and the New Partnership for African Development, which need not only to be more involved, but also to take the lead.

Sub-Saharan Africa specifically requires increased support to strengthen its existing DOTS programs. Staffing needs to be increased. The entire range of health providers, including private and NGO sectors, as well as community members needs to be engaged.

Third, close collaboration is vital between TB and AIDS control programs to deliver joint TB–HIV activities. As Ms. McCollum has emphasized, both HIV and TB programs need to be doing additional things to their usual forms of work in order to address the joint problem.

Fourth, financial resources are certainly needed. We provisionally estimate in WHO that about 30 billion U.S. dollars will be required between 2006 and 2015 for global TB control activities, if we are to achieve the MDG targets and this would avert an additional 2.5 million new cases and 2.5 million deaths globally.

Of this, nearly 9 billion U.S. dollars is required for Africa to avert an additional estimated 700,000 new TB cases and 1 million TB deaths.

Fifth, relatively small amounts are needed to catalyze the work of these new funding mechanisms and enable their resources to flow more rapidly.

There has been a massive request from countries for international technical assistance and agencies, such as the World Health Organization and other members of the Stop TB Partnership are finding it difficult to meet these requests.

Lastly, because of the longer term gains promised, as we have already touched on, investment in research and development for new vaccines, drugs and diagnostics is vitally important.

In conclusion, Africa is in desperate need of a significant scaling up of TB control efforts. It is technically feasible. It lacks only the political commitment and the financial resources.

I thank you for your attention.

[The prepared statement of Dr. Nunn follows:]

PREPARED STATEMENT OF PAUL NUNN, M.D., COORDINATOR FOR TB/HIV AND DRUG RESISTANCE, STOP TB DEPARTMENT, WORLD HEALTH ORGANIZATION

Chairman Smith, Ranking Member Payne and esteemed members of the Subcommittee,

On behalf of the World Health Organization, I thank you for the opportunity to brief you and the committee today and share our strategy for fighting the global TB epidemic. WHO has been at the forefront of the movement to control TB through the promotion of an effective TB treatment strategy, a single global plan, a single global monitoring and evaluation system (that reports each year to WHO), and a single, coordinated partnership. This Stop TB Partnership, hosted in WHO, is now an effective global movement of more than 300 partners pledged to accelerate social and political action to stop the spread of TB around the world. The US Government has made a major contribution to this partnership, especially through the highly valued work of the Centers for Disease Control and Prevention and the US Agency for International Development.

The global TB epidemic represents an enormous amount of human suffering, pain and grief. About nine million people around the world fall sick with tuberculosis (TB) every year and each year, two million lives are claimed by TB. The stigma attached to TB has serious psychological and social consequences. TB is inextricably linked to the HIV epidemic as TB is the major opportunistic infection and leading cause of death for people with AIDS.

The good news is that TB is treatable with drugs that cost about $10 for a six month course. With proper treatment, over 90% of cases are curable using the WHO-recommended treatment strategy, known as DOTS. Many countries have made a serious political commitment to implementing effective TB treatment strategies and have made steady progress in scaling up TB treatment programs. Between 1995 and 2003, 17 million TB patients were treated under the DOTS strategy with full engagement and commitment of Ministries of Health in182 (out of 210) countries of the world [1]. There has been significant improvement in the quality of detection, tracking, and reporting of TB cases globally in recent years, particularly in the Asia region. Both China and India have shown how DOTS can be rapidly scaled up and in 2003 notified nearly 1.7 million cases between them.

The Global TB Drug Facility, created in the year 2000 is a new mechanism for procuring high-quality, yet low-cost TB drugs for low-income countries. In four years alone, the GDF has provided TB drug supplies to over four million TB patients.

As a result of all these, and other, efforts, in five of six continents, the number of new TB cases is either falling or stable, and the Millennium Development Goals for TB (halving of the prevalence and mortality by 2015 compared to 1990) are likely to be met. Unfortunately, Africa is the one continent where TB rates are rising, sufficiently to cause an increase in global rates. WHO estimates that 2.3 million cases of TB occur annually in Africa, which reports 24% of the total notifications worldwide in a region with only 11% of the world's population. Of the 22 "high TB burden" countries which together constitute 80% of the global TB burden, nine are in Africa. They are DR Congo, Ethiopia, Kenya, Mozambique, Nigeria, South Africa, Tanzania, Uganda, and Zimbabwe. Of these, only South Africa has reached the World Health Assembly's TB control target for case detection. And none of these countries has reached the second TB control target of 85% treatment success. Globally both prevalence and mortality are falling, but not in Africa, where the TB–MDGs will not be met without a major scale up in TB control efforts.

HIV is the biggest single challenge to TB control efforts on the continent. In several African countries, including those with well-organized control programs, the crisis of HIV/AIDS has caused such dramatic increases in TB cases that the annual number of reported TB cases has risen more than fivefold since the mid 1980s. HIV infection is now the most important predictor of TB incidence across the African continent. At the same time TB accelerates the progression of HIV to AIDS. In 2003 over 80% of the global total of deaths among TB–HIV co-infected patients were in Africa. The life expectancy of an HIV infected person with TB is measured in weeks if treatment is not available.

Future projections are not optimistic. UNAIDS concluded that a fall in the numbers of HIV-infected people in Africa before 2010 is unlikely.[2] Currently, across the African continent 35% of TB cases are HIV-infected, although, in several African countries, these rates are much higher. For example, HIV levels in patients with TB in Namibia, South Africa and Zambia all stand at around 60% and in Botswana, the rate is 80%. This is compared to about 8% globally. As HIV rises, so the proportion of women diagnosed with TB increases, while their average age decreases.

In Bangkok in 2004 Nelson Mandela said "To fight against AIDS, we must do more to fight TB". So far this advice has largely gone unheeded, yet over half a mil-

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[1] World Health Organisation. Global Tuberculosis Control: Surveillance, Planning and Financing. Geneva, Switzerland, 2005. WHO/HTM/TB/2005.349

[2] UNAIDS. AIDS in Africa: three scenarios to 2015. UNAIDS, Geneva, Switzerland, 2005. UNAIDS /04.52E.

lion HIV infected people develop TB annually in Africa. They are also eligible for ART, and nearly 300,000 each year are already in contact with the health service. Thus, TB programmes are important entry points for ART scale-up. Availability of HIV testing and antiretroviral treatment in this population would help significantly towards reaching the goals of the US President's Emergency Plan for AIDS Relief notably those of treating two million HIV-infected people with antiretroviral drugs and providing care for ten million HIV-infected people.

TB is not only strongly linked to HIV, but also to poverty and the weak infrastructures and health systems that are its consequences. The low levels of economic performance in most African countries and the high levels of armed conflict and displacement of people create conditions of poor nutrition, crowding, and poor health service delivery that fuel transmission of the disease. In sub-Saharan Africa, it is estimated that only 53% of the population has access to health services. Even existing health systems and services are weak and sometimes poorly organised. In these, TB control will not succeed until the general health services, TB control program staff and other disease specific programs work together to address the basic priorities. But health sector reform must be carefully handled: priority setting at district level can sometimes exclude TB as a priority, and even compromise sound TB control activities, as in Zambia in the 1990s.

The lack of sufficient trained staff is consistently cited as the main constraint facing TB control. The quantity, competencies and distribution of staff are all important elements of an effective TB program. Health workers constitute the heart of the health services, yet in Sub Saharan Africa there is only about 1 health worker per 1000 population. The global average is 4, while it is 10.9 for North America. Time for planning, supervision and management is limited, and is all too often absorbed by uncoordinated missions of bilateral and multilateral funding agencies, and their technical counterparts. DOTS programs can do much more to engage the full range of health care providers (including all public providers, NGOs and private practitioners) as well as community members.

Multidrug-resistant tuberculosis (MDR–TB), although a serious threat to global TB control, is not yet a serious problem for TB control in most of Africa.

Despite considerable increases in the funding made available for TB control by the governments of the high TB incidence countries and of the donor countries, almost all African countries still face a shortfall in the funding needed to reach the global targets. Statements of political commitment by government leaders must be matched by concrete support in terms of increased funding. The Global Fund to fight AIDS, TB and Malaria is a significant innovative forward step, and will make a large contribution towards TB control if it can ensure rapid movement of the funding to where it can be used.

What then are the priorities?

In a nutshell, more resources still need to be mobilized for expanding the progress in the fight against TB; leaders everywhere, including in Africa, need to move from awareness to commitment and commitment to action; and a small amount of funds needs to be allocated specifically to support international technical assistance to countries for TB program design and monitoring.

First, unprecedented co-ordinated efforts by governments, donors, technical agencies and other stakeholders are urgently needed in Africa, in close collaboration with National TB and AIDS Control Programs. Progress depends on raising the profile of TB on political and development agendas, and mobilizing increased political commitment and funding among African countries. Pan-African institutions such as the African Union and the New Partnership for African Development need to be more involved. TB is estimated to cause an economic loss of 4–7% of GDP annually in countries with a high burden of TB and the disease is closely linked to poverty. It ought therefore to be more often incorporated in Poverty Reduction Strategy Papers (PRSPs) and in debt relief arrangements for the Highly Indebted Poor Countries (HIPC).

Second, sub-Saharan Africa specifically requires increased support to strengthen its DOTS Programs. This requires increased staffing, specific measures to retain staff once recruited, and a huge increase in training. Full engagement of the entire range of health providers including the private and NGO sectors is important to increase access to DOTS. Regulatory and legislative reform may be necessary to ensure this can happen. Communities need also to be engaged, especially in rural areas, and other marginalized segments of society. The role of community members in provision of diagnostic and care delivery services needs to be developed.

Third, close collaboration is required between National TB and AIDS Control Programs to deliver joint TB/HIV activities, including provision of HIV testing to TB

patients, provision of ARV treatment[3] and screening for TB among HIV service clients. TB/HIV collaboration has a particularly large impact on reducing the mortality from TB.

Fourth, the resources available for TB control should be increased and sustained. The STOP TB Partnership is currently developing a second global plan, for the period 2006–2015, to achieve the MDG TB targets with the eventual aim of eliminating TB as a public health problem. Provisional cost estimates indicate that about $30 billion USD, or an average of $3 billion per year, will be required between 2006 and 2015 for global TB control activities to achieve the MDG TB targets. The DOTS strengthening and TB/HIV components alone would avert an additional 2.5 million new TB cases and 2.5 million TB deaths globally. Of this, nearly $9 billion USD is required for Africa to avert an additional estimated 700,000 new TB cases and 1 million TB deaths. The current global funding gap for all countries is of the order of $1 billion per year.

Fifth, relatively small amounts are needed to catalyze the work of new funding mechanisms such as the Global Fund, and enable their resources to flow more rapidly. There has been a massive request from countries for international technical assistance and support in planning and building capacity to implement TB control activities and monitor progress. However, there has been only a minimal increase in dedicated funding to help provide this complementary technical support to countries. Stop TB partners, including WHO, have had difficulty in responding to this overwhelming demand. The additional resources required for providing these international technical inputs to program design and monitoring have been estimated globally at approximately $50 million per year, of which only $25 million was available in 2004. Scaling up activities aimed at greater TB/HIV collaboration, increasing public and private sector involvement and other initiatives will further increase the need for technical support.

Sixth, because of the longer term gains promised, investment in research and development of new vaccines, drugs and diagnostic tools is also important, provided that research and development efforts address the specific needs of those who are HIV infected.

In conclusion, Africa is in desperate need of a significant scaling up of TB control efforts. It is technically feasible, lacking only the political commitment and the financial resources.

I thank you for your attention.

Mr. SMITH. Dr. Nunn, thank you very much for your testimony and for being here at this, in your case, briefing. We do appreciate that and it does help this Committee be more effective in trying to provide the resources that are required to win this very important fight. Thank you for your insights and counsel.

Mr. N'Dour, without objection all of your written testimonies will be made part of the record. You make a very good point about the solution to the rise of drug resistent malaria parasites being the ACTs.

I was wondering if you might speak to—and Dr. Nunn, you might want to do this as well—to the issue of new products that might be provided.

ACT does provide a very effective line of defense. Mr. N'Dour, could you also speak to the issue of DDT? You say in your written testimony that it remains the most effective option we have in some situations, and we must continue to use it. You give examples of Mozambique, South Africa and Zambia that have dramatically or drastically—your word—reduced malaria infections with relatively little cost.

Obviously the DDT part of this remains, rightly or wrongly, controversial because of the stigma attached to that insecticide.

Mr. Moeller, again talking about new products and tools in the toolbox to effectively treat malaria, what government testing has

[3] World Health Organisation. Interim Policy on Collaborative TB/HIV activities. WHO/HTM/TB/2004.330 and WHO/HTM/HIV/2004.1

your product been through? What is the toxicity of your products and can they be made into a vaccine? What is the cost per cure of your product?

Again, I only discovered the existence of it recently, when you came and provided some insights about it. I had not heard of it before and it seems to me that we need to have a net as wide as possible to capture new, innovative products that might be effective in solving this problem or curing malaria and perhaps other diseases.

Mr. N'Dour, if you can begin.

Mr. N'DOUR. Thank you. Thank you, Chairman. What I think is, you know, we have three points. The first is, what we can do now and I think the solution we have is people need bed nets firstly, before all this debate about medicine, about, you know, the conclusion about how to kill the mosquito.

What I feel is really the ACT is really something we can use, but the mosquito net is very important. Bed net is very important.

Mr. SMITH. Would you mind suspending for one moment? Regrettably, I have to manage a resolution on Cuba that is coming up in about 5 to 10 minutes.

Mr. Fortenberry is going to take over the Chair, but please, could all of you answer those questions? Then, of course, Mr. Payne will have his shot. Thank you.

Mr. FORTENBERRY [presiding]. Dr. Nunn, did you wish to proceed with that question?

Dr. NUNN. Thank you very much. I understand the question to be asking what new products are in the pipeline and what mechanisms are there for ensuring there are new products in the pipeline to address drug resistance in tuberculosis.

As we have already heard, for a long time there has been little interest in the pharmaceutical industry or I should say the large research-based pharmaceutical industry.

In the last 4 or 5 years, a number of public/private partnerships have been established, particularly with funding from the Bill and Melinda Gates Foundation and involvement also of the Rockefeller Foundation, in the formation of the Global Alliance for Anti-TB Drug Development, based in New York, which is specifically charged with looking at new products and indeed, there are a number of new products in the pipeline.

Some are based on established classes of antibiotics, which turn out to have activity against tuberculosis and some are based on new products, new compounds which have come out of basic research, particularly following the discovery of the G-nome in tuberculosis and there are similar public/private partnerships in the area of diagnostics and in vaccines. Thank you.

Mr. FORTENBERRY. Mr. Moeller, did you care to answer that question as well?

Mr. MOELLER. Thank you. My question was what government testing has our product been through. Since we are a private company and have funded our programs separately, we have gotten some assistance from the government.

In the case of testing, for instance, for SARS that test was done through the National Institute of Health. In other testing that we have done, since the question has always come up—Is silver toxic or could it be toxic?—we have done an LE–50 test, which is a gov-

ernment test that was designed to determine whether something was toxic.

The animals involved in this toxic study were treated with 200 times the amount of the product that a person would ingest and the report from the doctor was that all the animals were healthy and, I would like to say happy, when the test was over with.

The test was very effective and we have done that now with quite a number of universities, in-vitro type tests. We have just been involved in a big study that has gone on at Penn State, which has been followed up at Arizona State, University of Arizona.

Most of the work that has been done along with people has been done in Africa. I cited the original, which happened that a member of the CIA gave these bottles to this doctor in Rwanda, who used them on the children and that started us off in the African program.

We have, since then, as you will know from my testimony, dispersed 1,000 bottles to several hospitals in Ghana and since we know silver is nontoxic, the test was conducted and turned out to be, as far as we can tell, 100 percent effective. Typically nothing is 100 percent effective, but to the best of our knowledge, the test worked.

So then we went back and have done specific tests now where the doctors control the patients. In other words, the patient comes in, gets a blood test. If it shows that he has malaria parasites in his blood, then he starts taking our silver product and we do about an ounce per day in divided doses.

Typically it takes about 3.4 days for that parasite to be out of the blood and we in fact, in these tests, do a blood test every day and the tests continue for 14 days. Typically we give the silver to the patient for 7 days and then every day after that, a week after that we test their blood every day.

When I say we, I am talking about the doctors in Africa. The tests are available. We have submitted it with our program. Today, this very day, we just got another group in from one of the other cities in Ghana, where doctors have been testing it.

They are certified results saying that they gave the person this ounce per day for several days and all of the patients that we are aware of were free of the parasites. Consequently, they felt better almost immediately.

The next question is what we talked about in toxicity, talking about the cost of the product. In the United States, we sell the product as a health supplement. We have sold hundreds of thousands of bottles and it sells for between $25 and $28 in a store.

Wholesale would be half of that and we have a special program that we have designed for Africa specifically, because we think we can make a difference there and that price is $4 for an 8-ounce bottle, which is about the cost of eliminating malaria for a single person.

What we have just done, I alluded to it, we are planning on doing a 600-patient study in Senegal, along with the University of Senegal in Dakar. We have passed it by members of the World Health Organization. All doctors, several doctors in Senegal have signed off on it.

Protocol is finished now and in Senegal they have a company that is owned by, at least part owned by, an Austrian or by the Government of Austria. The Government of Austria said to us that they will fund the test.

In fact, if it wouldn't be for the fact I was here with you today, I would be in Austria speaking with the government.

Mr. FORTENBERRY. Sorry about that.

Mr. MOELLER. Well, it would be fun. Anyway, they have agreed to fund the test, because this factory they have there, 30 percent of their workforce is off any given day because of malaria, and their doctors are aware of what we have been doing and they said, "Okay, let's fund it. Let's use a big enough number so that we can tell what is going on."

There are going to be 330 people using our product and 330 people taking a product that is currently used over there, and I am not sure whether it is chloroquinine, but whichever product is the most common over there is the one that is used.

Then there will be 300 people who do not have malaria who will be taking the silver, which is designed to be a prophylactic. We will find out if a person taking a little bit of this every day, if it will prevent him from getting malaria.

Mr. FORTENBERRY. Thank you very much for that insight.

Dr. Nunn, perhaps you might want to comment on how that cost compares to other conventional methods, if you wish.

Dr. NUNN. I would prefer to stay out of the malaria field, being more converse in tuberculosis, if you don't mind.

Mr. FORTENBERRY. I understand.

Mr. Payne, do you have any questions?

Mr. PAYNE. Just let me say that I am very excited about your test and we would certainly like to follow up from the Committee's standpoint to evaluate as you get the results. I mean what you have described seems like a blessing in disguise.

Mr. Moeller, we will certainly be in touch through the Chairman to find out how the program is progressing. It sounds very exciting.

Mr. MOELLER. Thank you. We would be pleased to report.

Mr. FORTENBERRY. One more question, Mr. Moeller. Can you explain the difference between your product and ACT?

Mr. MOELLER. No. ACT is a drug. I mean we are a supplement made up of just silver and water. It is very basic. We have been able to re-engineer the silver and the water so they come together as an active molecular product.

If you compare it to ACT, ACT is toxic. If you take it, it makes you sicker, at least a lot of people who take it get sick.

Ours is available to children and adults. It is simply not toxic in any form that we have ever found and so if a child takes it, as we have given an example here, it is not toxic to the child. They don't end up throwing up or diarrhea or any of the common things that are associated with antibiotics and other products that are designed as health care.

Mr. FORTENBERRY. Perhaps you would like to venture into the question about cost differentials? If you don't have that information readily in front of you, that is fine.

Mr. MOELLER. What the silver costs against ACT?

Mr. FORTENBERRY. Correct.

Mr. MOELLER. I am not in a position to address that, because I don't know what the costs are. I know what ours is and it is pretty basic: $4 a bottle is what we ship it to Africa for.

Mr. FORTENBERRY. Excellent. Gentlemen, we thank you very much.

Mr. PAYNE. Excuse me, Mr. Chairman. I have a couple more questions if you don't mind.

Mr. FORTENBERRY. Sure. Absolutely.

Mr. PAYNE. Thanks. Mr. Smith usually lets me go on, so if it is all right if you would.

Let me just ask, first of all let me also commend you, Mr. N'Dour, for the work that you have done and to be a UNICEF Ambassador, that is quite a distinction.

When I was a youngster, the first UNICEF Ambassador was a fellow named Sammy Kay and that was after World War II and we have seen older people, gray-haired people would remember Sammy Kay. Your hair should be like mine. Ladies here never get gray like men for some reason.

Have you seen, being Senegalese, have you seen an interest on the part of African entertainers and athletes and people of prominence to get involved in some of the issues like you have or are you sort of an anomaly?

Have you seen your colleagues become more interested and attempt to be advocates for issues like fighting tuberculosis, fighting malaria, having transparency in government attempting to stop conflict, these issues as an African?

Mr. N'DOUR. Thank you. I think really what I mentioned before is, I was not in my own alone during this Africa life. There were more than 20 band and leaders really well-known in Africa, speaking different languages, coming from different countries, different places and they, I believe, realized people get the message.

Even me, 1 year ago, I was in the same position like a lot of people. I meet people who battle malaria and talk about malaria and they tell me the danger and give me all the information and that day I have my engagement and I follow to fight against malaria.

I think also the same thing is happening with my colleagues and the sport people, a lot of people during the Africa life join us to say, okay, we support you and we get the message.

We are going to deliver the message to the villageside and we have also coming program like the caravan we really want to organize in Africa, everywhere playing music with local band and joint sport and tell people how important.

We feel what I say before, you know, in fact of this problem in our economy is making the politician, you know, more following the fights against malaria. I think it is important.

What I feel is people already know and, you know, sometimes in Africa when people talk about these kinds of things, they say if U.S. want to fight these things, things going to happen and this is symbolized by my staying here and people saying, okay, like AIDS, like malaria, like TB, if the U.S. Government or the Congress and the American people want to follow the fight and fight against the things, we are going to miss it.

The real message coming from the roots people in Africa and sometimes I believe it, because the work people doing here, the

U.N. Foundation and Global Fund, Roll Back Malaria and today the things happening here make me really positive about, you know, puts the things behind.

Mr. PAYNE. Thank you very much. Once again we certainly appreciate what you have done.

Dr. Nunn, let me just conclude by, as we have mentioned there has been a 20 percent drop in TB since 1990 around the world, but it has tripled in Africa and so we know that we really have a very serious problem there. About a third or 1.7 million TB deaths a year occur in Africa.

Of the nine high burden countries in Africa, only South Africa has reached the World Health Assembly TB's control target.

There was a big meeting in Abuja, as you know. Forty-four heads of state or their representatives. The Abuja declaration halving malaria deaths by 2010, having 60 percent coverage for malaria prevention and control by 2005.

Are there any sub-Saharan countries that you can point to that there is some progress being made? Evidently, we are sort of off the mark and do you see us reconvening the group to try to find out what must be done to try to get on target, since we are so far off target as relates to TB?

If those countries are doing, any country you can think in terms of in sub-Saharan Africa that may be winning, at least stabilizing the battle.

Dr. NUNN. Thank you, Mr. Chairman. There are in fact a number of African countries that I think are, all things considered, performing extremely well. I mean given the pressure of HIV, putting the case number up.

Many of the countries in Eastern Africa, particularly where HIV is highest, such as Malawi, Kenya, Tanzania, are doing really quite well, given the resources at their disposal, to maintain their TB treatment system.

However, because of the presence of HIV, they need unfortunately to have to do more in order to do the additional things that Ms. McCollum mentioned earlier.

One of the possible good things on the horizon is that although globally HIV is not expected to fall greatly before 2010, there are some countries in which incidence appears to have peaked and in those countries we are now beginning to see TB flattening off a little bit.

That is a bright spot on the horizon, but it should not lead to any complacency in trying to scale up joint TB–HIV activities.

You speak of the political processes within Africa and touch on Abuja. In actual fact, next week there will be a meeting of the Stop TB Partnership Coordinating Board in Addis Ababa, Ethiopia, in which for the first time the President of the African Union will be attending, Mr. Konare, as well as the Prime Minister of Ethiopia, Mr. Meles Zinawi.

Our intention is that this meeting should mark a considerable increase in the political attention being given to tuberculosis.

What is happening at the moment is that African leaders very often mention HIV/AIDS. Now they have been persuaded to do that. They often mention malaria, because it is a disease everybody knows and recognizes and suffers from.

But TB remains something of an orphan in this respect and I think if progress is to be made, particularly in Africa, we have to break through and achieve visibility of tuberculosis at the political level.

We are putting forward the proposition in Addis that in 2006 there should be a summit on TB financing in Africa, which may take place within the next Stop TB Partners Forum, which takes place every 2 years, which is also now intended to be in Africa.

All of this is to draw attention to the fact that if we are to achieve Millennium Development goals globally, we have to pay more attention to Africa.

So I think to answer your question, Mr. Payne, there are many processes in train trying to keep up the political momentum on TB control in Africa.

Mr. PAYNE. Let me thank all of you. Thank you for that. I do think that Napad and the new AU, there is an opportunity to see things happen differently.

I had an opportunity to visit Addis several months ago and meet with Secretary-General Konare and his staff and I do have high hopes.

Just concluding that, you know, if we are going to fight the war on terror, countries that have a weak system, weak health system can be more easily influenced, I think, by wrongdoers and as we move toward a globe of democracy, as the President talked about, we are not going to be able to do it having as paraphrase Abraham Lincoln, you can't have a world half healthy and a world sick. It has to come together in this global village.

I appreciate all of your testimonies. Thank you.

Mr. FORTENBERRY. Thank you, Mr. Payne.

Ms. McCollum, do you have any further questions?

Ms. MCCOLLUM. Just a comment. I really appreciate the energy that our Ambassador has brought forward in getting the message out about malaria and Roll Back Malaria is working on some exciting partnerships in Africa and Tanzania, with technology for bed nets, with African companies selling to Africans is very exciting.

Then as UNICEF and other organizations continue to work to launch agricultural projects to have access available to making the drugs in Africa by Africans for Africans is very exciting.

I would like to take an opportunity to clarify something that was entered in the record before you were here, Mr. Chair.

There were comments made about PSI, which is a nonprofit group, Population Services International, about implying somehow that there was price gouging going on with different prices being charged for nets.

I will give an example of how efficiently and effectively PSI has tried to be. For example, in Malawi in 2004, PSI sold 1.5 million bed nets, of which 36 million were sold for 50 cents U.S. to pregnant women.

The remainder of those nets, 100,000, were sold at commercial market rate. In other words, what the market will bear. There were two brands of nets right next to each other. So it is what the market will bear.

What PSI did in those cases at the market rate is that they recovered costs. In return, that allowed them to subsidize even more nets, making more nets available to more families.

The real cost of the nets sold at a subsidized rate is 50 cents. Market value you might find $5 to $7. It is what the market will bear. It is not the only net that is available. It is side-by-side by another company that is selling for the same market rate.

But by taking these dollars at the market rate and, as I said, recycling them, it helped Malawi—which is not a PEPFAR country—it helped Malawi reach the goals of covering 60 percent of the pregnant women and children under 5 years.

We were able to see more people being covered by PSI being very prudent, by being very effective and very careful in making sure that those who could afford to buy nets bought them, but those dollars that those African families that could afford to buy the nets went in to help other African mothers and children who could not afford.

So I just thought it was important to set the record straight, Mr. Chair, and thank you for giving me an opportunity to do that.

You are shaking your head, Mr. Ambassador. Am I correct? Thank you. He says I am correct.

Mr. FORTENBERRY. Thank you. I believe that concludes our questioning and I wish to thank Dr. Nunn and Mr. N'Dour. Thank you. You have both come a very long way to be with us and we are most grateful.

Mr. Moeller, thank you for your time and your insightful testimony today. We are very, very appreciative of your passion, your interest and your dedication to helping resolve these important health problems. Thank you so much.

We are adjourned.

[Whereupon, at 4:10 p.m., the Subcommittee meeting was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

RESPONSES FROM MR. MICHAEL MILLER, DEPUTY ASSISTANT ADMINISTRATOR, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT, TO QUESTIONS SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS AND INTERNATIONAL OPERATIONS

Question:

In which African countries does USAID support a program of DDT spraying and bed-nets? Please provide the list of countries and a description of the programs, including amounts of funding.

Response:

USAID supports national malaria control programs in about 22 countries in Africa. In seven of these country programs, USAID is helping both implement indoor residual spraying (IRS) and the use of insecticide treated nets (ITNs), or bednets. For several of these country programs, DDT is the insecticide used for IRS. The information below outlines the insecticide used for IRS by the national program in each country where USAID supports IRS and ITNs, as well as a brief description of USAID's support.

The countries where USAID supports a combination of IRS and ITNs for prevention of malaria include: Eritrea, Zambia, Mozambique, Uganda, Liberia, Angola, and Burundi. In addition, USAID supports IRS in Kygyzstan in Central Asia.

In Eritrea, the National Malaria Control Program uses DDT and Malathion for IRS. USAID supports an integrated program including targeted spraying, improved treatment, larval control, and ITNs with strong emphasis on monitoring and evaluation. USAID's total support for malaria in FY04 was $600,000, of which $420,000 was directed targeted IRS, ITN and larval control interventions.

In Zambia, the National Malaria Control program uses DDT and synthetic pyrethroids for spray operations. USAID supports a comprehensive program including treatment, prevention and malaria in pregnancy. For IRS, USAID supports the training of spray teams; training for logistic planning, and monitoring. ITN support includes delivery through the commercial sector and targeted subsidization of ITNs to high risk rural poor. For the last several years USAID funding has been about $4 million per year. In FY 2004, $1.3 million was directed at IRS and ITN delivery.

In Mozambique, the national program uses Bendiocarb for spray operations. USAID support includes improved management and surveillance, treatment, epidemic preparedness and prevention. For IRS, USAID has supported management training, an advisor, equipment purchases, and monitoring. For ITNs, USAID has provided small grants to NGOs and ITN distribution in the north. Annual USAID funding for malaria has ranged between $1.5 million to $500,000 per year for the past four years. In FY 2004, total USAID funding for malaria was $1.5 million, of which $600,000 was directed to prevention, including commodities for the IRS spray teams ($71,640 for Hudson spray pumps and parts; $24,689 for protective clothing for spray teams; and $10,997 for motorcycles for spray teams).

In Uganda, USAID has provided support for IRS programs including technical assistance for training, planning, implementation and the monitoring and evaluation of the IRS program. USAID also supports a national effort to expand delivery of ITNs through the commercial sector, delivery of subsidized nets to the high risk rural poor, and a targeted voucher program to deliver nets to pregnant women through antenatal clinics.

In Kyrgyzstan, the national program uses Cyfluthrin for spray operations. USAID supports an integrated malaria control program including IRS, larval control, and improved treatment. For IRS, USAID support includes procurement of insecticides, purchase of equipment for spray teams and protective clothing for teams. In FY 2003, $776,310 was directed to malaria, of which $230,000 supported IRS activities (including commodity procurements). In 2004, $176,000 was provided for malaria efforts.

In Liberia, USAID support for malaria focuses primarily on ensuring prompt and effective treatment; however, through Office of Foreign Disaster Assistance (OFDA) funding, USAID is currently reviewing a proposal by Malaria Emergency and Technical Operational Response (MENTOR) which includes both IRS and ITNs. Currently, synthetic pyrethroids are used for spray operations in Liberia. Total funding for malaria is about $300,000 per year in addition to an estimated $700,000 from OFDA for the MENTOR proposal.

In Angola, the national program utilizes synthetic pyrethroids for spray operations. USAID supports a comprehensive program including treatment, prevention and malaria in pregnancy. For IRS, USAID supports the National Malaria Control Program's effort to implement IRS in epidemic prone areas, including purchase of safety clothing for IRS sprayers. USAID also supports social marketing of ITNs in targeted provinces. Total USAID funding for malaria is $1 million per year in addition to funding from OFDA, estimated to be $500,000 for a grant to MENTOR for malaria activities, including IRS and ITNs.

In Burundi, synthetic pyrethroids are being used for spray operations by the national program. USAID supports a broad program including treatment, prevention and malaria in pregnancy. Support for ITNs is on-going. In 2003, USAID supported IRS implementation implemented by Medecins Sans Frontieres. Total USAID funding is between $400,000 and $500,000 per year.

Question:

At the recent Southern African Malaria Control meeting in Gabarone, Botswana, allegations were made that USAID was putting pressure on the Malagasy government to fund PSI, a USAID contractor which proposed to sell bed nets to Madagascar at twice what it would cost the government to do itself. Please explain USAID's position on this issue, and provide details about how USAID is monitoring its bed net program to ensure that the most bed nets are made available to protect the most people.

Response:

This allegation is false, and is based on a gross misrepresentation of the issue in Madagascar. USAID did not pressure the Malagasy government to fund Population Services International (PSI), and PSI did not propose to sell nets at twice the cost that the government could do itself. USAID Missions routinely discuss pricing issues as part of the design process of any activity which includes distribution of insecticide-treated nets (ITNs), and monitor market prices as part of routine project oversight.

The actual issue in Madagascar was on how ITNs funded through a Global Fund grant were to be distributed.

The Global Fund approved a proposal from Madagascar for a coordinated strategy for ITNs, including cost recovery and targeted subsidization of nets. The proposal includes specific language stating that ¾ of the ITNs would be sold at subsidized prices, and that ¼ would be distributed free through the government's health facilities to those too poor to pay for nets. The Global Fund proposal was approved by all the members of the Madagascar Country Coordinating Mechanism (CCM), including representatives from the Madagascar Ministry of Health, USAID, the World Bank, UNICEF and WHO, among others. PSI was designated as the Principal Recipient for this grant.

Shortly after the proposal was reviewed by the Global Fund, a newly appointed Minister of Health in Madagascar decreed that the Global Fund ITNs would all be distributed free of charge. As this was a significant change in the proposal, the Global Fund manager for the Madagascar grant stated such a change would require a re-review of the proposal by the Global Fund's Technical Review Panel.

USAID's position was that any substantive changes in the implementation plan or proposal must be approved by the CCM and not executed unilaterally, in keeping with a central premise of Global Fund procedures.

Subsequently, all parties agreed to a revised division of distribution methods, with more than ½ of the nets being distributed for free. This compromise was brokered by USAID's health team, and USAID fully supports the Government of Madagascar

policy on net distribution. The implementation of the Global Fund activity is now beginning in Madagascar.

We are unaware of details or calculations leading to the allegation that nets would be sold by PSI in Madagascar for "twice the price." The "twice the price" language most likely refers to the common practice of "cross-subsidization", in which full market-price goods are sold in urban area shops to those who can afford them, and the proceeds used to subsidize free or very low-cost nets for the rural poor. Segmenting the market in this manner increases the efficiency of subsidies, ensuring that more of the donor funds are directed to those in greatest need, the rural poor. This market segmentation also ensures that operating costs are available to sustain the ITN supply process, giving greater sustainability for the long-term.

With regard to prices of nets, it is USAID's policy that economics should never be a barrier to ITN use. USAID staff members carefully monitor programs and work closely with partners in each country to ensure that any nets purchased with USAID funds are distributed in a manner that works to reduce economic barriers to ITNs to the maximum extent possible. Market prices of ITNs are frequently checked as part of this on-going monitoring.

RESPONSE FROM MR. WILLIAM D. MOELLER, PRESIDENT AND CEO, AMERICAN BIOTECH LABORATORIES, TO QUESTION SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HUMAN RIGHTS AND INTERNATIONAL OPERATIONS

Thank you, Chairman Smith, for asking me to compare ABL's engineered, metallic silver nano-sized particles in water (ASAP), with artemisinin-based combination therapies (ACT's) for the treatment of malaria. While ASAP and the ACT's have a few similarities, the ACT's differ in a number of significant ways from ASAP, and depending on the circumstances, ASAP may be far more useful for a variety of public health, medical and humanitarian efforts at home and abroad.

ASAP and artemisinin are similar in that they both have their origins in the traditional medical practices of ancient cultures. Silver was used for its inherent antimicrobial properties by the ancient Egyptians and in the Ayurvedic medicine of India for thousands of years. Artemisinin is a derivative of an ancient Chinese herbal remedy for fevers—a plant called sweet wormwood—and likewise has been used for thousands of years[1].

The raw materials from which ASAP is derived are water and silver, both in abundant supply in the US. For example, ABL has access, through Clifton Mining alone to 33 square miles of mines; representing several million ounces of silver. ABL and Clifton collectively possess the skills and resources needed to produce ASAP from the ground up, without needing to consider implications of foreign trade policies, political instabilities, or interruptions to the flow of raw materials. The basic raw material for the production of artemisinin, on the other hand, is the sweet wormwood plant grown primarily in China and Viet Nam[2]. Production of the ACT's is thus dependent on the supply of sweet wormwood from these countries, and is vulnerable to interruptions in supply of the plant, crop failures, etc. Raw material supply problems have already caused interruptions in the anticipated supply of some ACT's[3].

Once produced, ASAP has a shelf life estimated to be six (6) years or more. This allows for the storage and stock-piling of ASAP on a large-scale basis. With an increase in production facilities, lead time is not an issue with ASAP. The ACT's and artemisinin on the other hand, have a shelf life of only 2 to 3 years. Long term stock-piling of the ACT's cannot take place and further, the shorter half-life of the ACT's creates the need for strict control of the supply chain to avoid stock outs, waste or improper use[4].

ASAP is a broad spectrum anti-microbial with demonstrated effects against a wide variety of organisms including *B. subtilis* (a surrogate for Anthrax testing), numerous Staphylococcus species (including "flesh eating bacteria"), *E. coli*, Salmonella, bovine tuberculosis (a surrogate for human tuberculosis testing), and various fungi and viruses. ASAP has also been used in the treatment of babies, chil-

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[1] The Journal of the American Botanical Council, HerbalGram, 2004; 64:19–20

[2] *"The Use of Artemisinin & its Derivatives as Anti-Malarial Drugs"*, World Health Organization, WHO/MAL/98/1086

[3] *"Update on world antimalarial drug supply"*, World Health Organization, Roll Back Malaria Department; Nov. 8, 2004.

[4] *"Procurement of Artemether-Lumefantrine (Coartem®)* Through WHO", World Health Organization, Roll Back Malaria Department.

dren, adults and the elderly for both complicated and uncomplicated malaria and also after traditional antimalarial drugs failed (i.e. drug resistant cases). The broad spectrum of ASAP makes it an ideal agent for a variety of anti-microbial uses, providing almost unparalleled flexibility for health care planning and logistics. The ACT's, however, are indicated only for the treatment of malaria (and in some instances only for the treatment, for example, of uncomplicated falciparum malaria) and cannot be stock-piled for other alternative uses.

Once administered, ASAP's engineered, metallic silver nano-sized particles function as single agent, medicinal catalysts with no known side effects. ACT's conversely, are, by definition, combination therapies and use two or more anti-malarial agents at the same time, many of which cause side effects in up to 40% of patients such as dizziness, headache, abdominal pain, loss of appetite, nausea, vomiting or diarrhea.

While the cure rates at 14 days are similar[5] for ASAP (100%) and the *best* of the recently tested ACT's (artemether-lumefantrine at 99%, with amodiaquine—artesunate a distant second at 89%), the higher incidence of side effects with ACT's may significantly impact their use as prophylactics against malaria. Since there are no known side effects from ASAP, it is anticipated that small daily doses of ASAP can also be taken long term as an antimalarial prophylactic, without producing side effects. Currently, travelers and residents in high risk malaria areas rarely use long term traditional or ACT prophylaxis, mainly due to the side effects and complications from the antimalarial drugs[6].

Much time and attention has already gone into assessing the affordability and financing of ACT's[7]. The costs of various ACT antimalarial options range from $2.30 to $3.60 per adult treatment and it is anticipated that ACT's are likely to have affordability and pricing problems7. Antimalarial treatment costs are a huge burden to countries where malaria is endemic and many African counties spend about one third of their health budget on this single disease.

On the brighter side, current pricing for ASAP is about $2.50 per adult treatment and it is anticipated that there will not be affordability or pricing issues in regards to ASAP, especially for humanitarian efforts such as the treatment of malaria. In addition to the likelihood that the cost of an adult ASAP treatment for malaria is apt to *decline* as ABL's production and distribution capabilities increase and expand, ASAP is also a broad spectrum anti-microbial and thus burdened nations utilizing this option would no longer find themselves dedicating a significant portion of their health care budgets to a single disease.

Overall, while there are a few similarities between ASAP and the ACT's, the differences between the two make ASAP a viable, realistic and a much more reliably available alternative to the ACT's in the fight against malaria. The ACT's have potential raw material supply problems, have a comparatively short shelf life, are narrow in anti-microbial spectrum, have side effects both during treatment of malarial fever and as prophylaxis, and require dedication of a significant portion of the health care budgets of stricken countries to this single disease, thereby limiting the growth and flexibility of many developing nations.

As a recent addition to the health care armamentarium, ASAP provides another alternative that was previously unavailable. There is an abundant supply of raw materials for ASAP, it has a longer shelf life and is very broad spectrum (having been tested against malaria as well as a variety of other organisms including many strains of bacteria, viruses, and fungi). These characteristics make ASAP ideal for stock-piling as a general anti-microbial agent, allowing quick response to outbreaks and unexpected events. ASAP has no known side effects and thus far has been well tolerated even in the critically ill, very young and elderly. It is likely that the price of ASAP for malaria relief efforts will come down as ABL expands its production capabilities and strategic alliances. ASAP and other similar ABL products represent a new alternative for developed and developing nations alike, for the treatment of many diseases as well as for improved health and wellness overall.

[5] Lancet, 2005;365:1439, 1474–1441, 1481–1483, 1487–1498

[6] *"Coartem®* Monograph", 3rd Edition January 04, Novartis.

[7] *"Improving the Affordability and Financing of Artemisinin-Based Combination Therapies"*, Malaria Control Department & Essential Drugs and Medicines Policy Department, World Health Organization, WHO/CDS/MAL/2003.1095.